

 PREVENTIVE genomics		CLIA ID: 45D2332030 Lab Director: Dr. Congying Gu		HEREDITARY THYROID DISORDERS RISK TESTING REQUISITION FORM		
INSTRUCTIONS			ORDERING PHYSICIAN INFORMATION			
<ul style="list-style-type: none">▪ Patient and Physician must sign the consent form▪ All items identified as 'Required' must be Provided/attached to the requisition form.			Physician Name		NPI#	FAX#
			Office/Practice/Institution Name		Physician's Email	
			Street Address			
			City		State	Zip Code
SUBMISSION CHECKLIST			Office Contact Name		Contact Phone	Contact Email
<input type="checkbox"/> SOAP notes and progress notes						
<input type="checkbox"/> Patient insurance ID card or face sheet						
<input type="checkbox"/> Physician and Patient Signature						
Ordering Provider (Please select one physician per order)						
Physician name:		Physician NPI:		Physician name:		Physician NPI:
Physician name:		Physician NPI:		Physician name:		Physician NPI:
PATIENT INFORMATION REQUIRED						
Patient First Name		Patient Last Name		Date of Birth (mm/dd/yyyy)		Phone Number
Address			City		State	Zip
Gender Identity		Sexual Orientation		Ancestry		
<input type="checkbox"/> Male		<input type="checkbox"/> Lesbian, gay, or homosexual		<input type="checkbox"/> White/Caucasian		
<input type="checkbox"/> Female		<input type="checkbox"/> Straight or heterosexual		<input type="checkbox"/> Middle eastern		
<input type="checkbox"/> Female-to-Male		<input type="checkbox"/> Bisexual		<input type="checkbox"/> Native American		
<input type="checkbox"/> Male-to-Female		<input type="checkbox"/> Something else (Describe)		<input type="checkbox"/> Hispanic		
<input type="checkbox"/> Gender queer		<input type="checkbox"/> Choose not to disclose		<input type="checkbox"/> African American		
		<input type="checkbox"/> Choose not to disclose		<input type="checkbox"/> Ashkenazi Jewish		
				<input type="checkbox"/> American Indian		
				<input type="checkbox"/> Asian		
				<input type="checkbox"/> Native Hawaiian and Other Pacific Islander		
PAYMENT OPTIONS (SELECT ONE) REQUIRED						
<input type="checkbox"/> Insurance Billing (Please provide the insurance information)		Primary Insurance		Insurance Policy/ID#		Group#
		Primary Policy Holder Name		Date of Birth		
		Secondary Insurance		Insurance Policy/ID#		Group#
		Secondary Policy Holder Name		Date of Birth		
<input type="checkbox"/> Self-Pay (Please provide credit card details or mail the check to the laboratory address)						
<input type="checkbox"/> Client Billing / Institutional Billing						
SPECIMEN INFORMATION REQUIRED						
Sample Type		Shipping Instructions			Send completed Requisition Form with collected sample to: 10700 Richmond Ave, STE 112 Houston, TX 77042	
<input type="checkbox"/> Buccal Swab <input type="checkbox"/> Extracted DNA		Label each specimen tube with the patient's full name and date of birth or patient's full name and collection date.				
Sample Draw Date (mm/dd/yyyy)/...../.....		To receive the specimen requirements and shipping guidelines, please send an email to - clientservices@preventivegx.com				
CLINICAL HISTORY						
Indications for Testing: <input type="checkbox"/> Diagnostic <input type="checkbox"/> Presymptomatic <input type="checkbox"/> Family History <input type="checkbox"/> Family Variant <input type="checkbox"/> Other:						
Age of Primary Diagnosis:						
Previous genetic tests: <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please specify the test and results)						
Will Patient management be changed depending on the test results? <input type="checkbox"/> Yes <input type="checkbox"/> No						
FAMILY HISTORY						
<input type="checkbox"/> No Known Family History <input type="checkbox"/> Pedigree Attached <input type="checkbox"/> Adopted						
Relationship	Maternal	Paternal	Relavant History			Age at Diagnosis
1	<input type="checkbox"/>	<input type="checkbox"/>				
2	<input type="checkbox"/>	<input type="checkbox"/>				
3	<input type="checkbox"/>	<input type="checkbox"/>				

<input type="checkbox"/> PIK3CA	<input type="checkbox"/> SLC5A5	<input type="checkbox"/> PAX8	<input type="checkbox"/> TGFBI	<input type="checkbox"/> ATP1A2	<input type="checkbox"/> PLN	<input type="checkbox"/> IRAK1	<input type="checkbox"/> CST3
<input type="checkbox"/> TRH	<input type="checkbox"/> CACNA1A	<input type="checkbox"/> GLIS3	<input type="checkbox"/> TG	<input type="checkbox"/> HRAS	<input type="checkbox"/> TFR2	<input type="checkbox"/> G6PD	<input type="checkbox"/> CST1
<input type="checkbox"/> THRB	<input type="checkbox"/> PRKCG	<input type="checkbox"/> FOXE1	<input type="checkbox"/> THRA	<input type="checkbox"/> TTR	<input type="checkbox"/> SLC26A4	<input type="checkbox"/> SLC16A2	<input type="checkbox"/> CSTB
<input type="checkbox"/> CTNNB1	<input type="checkbox"/> HAMP	<input type="checkbox"/> SECISBP2	<input type="checkbox"/> TP53	<input type="checkbox"/> IYD	<input type="checkbox"/> TSHR	<input type="checkbox"/> IGSF1	<input type="checkbox"/> DUOX2
<input type="checkbox"/> KRAS	<input type="checkbox"/> SLC40A1	<input type="checkbox"/> GNAQ	<input type="checkbox"/> TSHB	<input type="checkbox"/> HFE	<input type="checkbox"/> NKX2-1	<input type="checkbox"/> TBL1X	<input type="checkbox"/> RET
<input type="checkbox"/> DUOX1	<input type="checkbox"/> TPO	<input type="checkbox"/> PLCG2	<input type="checkbox"/> NRAS	<input type="checkbox"/> ESR1	<input type="checkbox"/> MECP2	<input type="checkbox"/> IRS4	

COMMONLY USED ICD10 (DIAGNOSIS) CODES

Please note, the icd-10 codes herein are solely for informational use. It is incumbent upon order practitioners to the diagnosis code that precisely justifies test conduct, regardless of its presence in the subsequent list.

Category - 1: ICD10 codes

<input type="checkbox"/> E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm	<input type="checkbox"/> E04.1	Nontoxic single thyroid nodule
<input type="checkbox"/> E03.3	Postinfectious hypothyroidism	<input type="checkbox"/> E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm
<input type="checkbox"/> E04.8	Other specified nontoxic goiter	<input type="checkbox"/> E05.10	Thyrotoxicosis with toxic single thyroid nodule without thyrotoxic crisis or storm
<input type="checkbox"/> E01.1	Iodine-deficiency related multinodular (endemic) goiter	<input type="checkbox"/> E06.2	Chronic thyroiditis with transient thyrotoxicosis
<input type="checkbox"/> E06.1	Subacute thyroiditis	<input type="checkbox"/> E06.5	Other chronic thyroiditis
<input type="checkbox"/> E06.0	Acute thyroiditis	<input type="checkbox"/> E06.9	Thyroiditis, unspecified
<input type="checkbox"/> E04.2	Nontoxic multinodular goiter	<input type="checkbox"/> E05.11	Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm
<input type="checkbox"/> C73	Malignant neoplasm of thyroid gland	<input type="checkbox"/> E05.20	Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm
<input type="checkbox"/> E05.30	Thyrotoxicosis from ectopic thyroid tissue without thyrotoxic crisis or storm	<input type="checkbox"/> E05.21	Thyrotoxicosis with toxic multinodular goiter with thyrotoxic crisis or storm
<input type="checkbox"/> E06.4	Drug-induced thyroiditis	<input type="checkbox"/> E05.31	Thyrotoxicosis from ectopic thyroid tissue with thyrotoxic crisis or storm
<input type="checkbox"/> E07.9	Disorder of thyroid, unspecified	<input type="checkbox"/> E05.40	Thyrotoxicosis factitia without thyrotoxic crisis or storm
<input type="checkbox"/> C75.9	Malignant neoplasm of endocrine gland, unspecified	<input type="checkbox"/> E05.41	Thyrotoxicosis factitia with thyrotoxic crisis or storm
<input type="checkbox"/> C61	Malignant neoplasm of prostate	<input type="checkbox"/> E05.80	Other thyrotoxicosis without thyrotoxic crisis or storm
<input type="checkbox"/> E03.8	Other specified hypothyroidism	<input type="checkbox"/> E05.81	Other thyrotoxicosis with thyrotoxic crisis or storm
<input type="checkbox"/> E03.9	Hypothyroidism, unspecified	<input type="checkbox"/> E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm
<input type="checkbox"/> E04.9	Nontoxic goiter, unspecified	<input type="checkbox"/> E05.91	Thyrotoxicosis, unspecified with thyrotoxic crisis or storm
<input type="checkbox"/> E06.3	Autoimmune thyroiditis	<input type="checkbox"/> E07.0	Hypersecretion of calcitonin
<input type="checkbox"/> E07.89	Other specified disorders of thyroid	<input type="checkbox"/> E07.1	Dyshormogenetic goiter
<input type="checkbox"/> L04.0	Acute lymphadenitis of face, head and neck	<input type="checkbox"/> E07.81	Sick-euthyroid syndrome
<input type="checkbox"/> R59.0	Localized enlarged lymph nodes	<input type="checkbox"/> E20.1	Pseudohypoparathyroidism
<input type="checkbox"/> R59.1	Generalized enlarged lymph nodes	<input type="checkbox"/> Z85.8	Personal history of malignant neoplasms organs and
<input type="checkbox"/> Z85.850	Personal history of malignant neoplasm of thyroid	<input type="checkbox"/> D02.0	Systems
<input type="checkbox"/> E03.0	Congenital hypothyroidism with diffuse goiter	<input type="checkbox"/> D09.3	Carcinoma in situ of larynx
<input type="checkbox"/> E03.1	Congenital hypothyroidism without goiter	<input type="checkbox"/> D14.1	Carcinoma in situ of thyroid and other endocrine glands
<input type="checkbox"/> E03.2	Hypothyroidism due to medicaments and other exogenous substances		Benign neoplasm of larynx
<input type="checkbox"/> E03.4	Atrophy of thyroid (acquired)		
<input type="checkbox"/> E03.5	Myxedema coma		
<input type="checkbox"/> E01.0	Iodine-deficiency related diffuse (endemic) goiter		
<input type="checkbox"/> E01.2	Iodine-deficiency related (endemic) goiter, unspecified		
<input type="checkbox"/> E01.8	Other iodine-deficiency related thyroid disorders and allied conditions		
<input type="checkbox"/> E04.0	Nontoxic diffuse goiter		

Category - 2: ICD10 codes

<input type="checkbox"/> C17.0	Malignant neoplasm of duodenum	<input type="checkbox"/> C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
<input type="checkbox"/> C17.1	Malignant neoplasm of jejunum	<input type="checkbox"/> C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
<input type="checkbox"/> C17.2	Malignant neoplasm of ileum	<input type="checkbox"/> C34.90	Malignant neoplasm of unspecified part of unspecified bronchus and lung
<input type="checkbox"/> C17.3	Meckel's diverticulum, malignant	<input type="checkbox"/> C34.91	Malignant neoplasm of unspecified part of right bronchus and lung
<input type="checkbox"/> C17.8	Malignant neoplasm of overlapping sites of small intestine	<input type="checkbox"/> C34.92	Malignant neoplasm of unspecified part of left bronchus and lung
<input type="checkbox"/> C17.9	Malignant neoplasm of small intestine, unspecified	<input type="checkbox"/> C38.4	Malignant neoplasm of pleura
<input type="checkbox"/> C18.0	Malignant neoplasm of cecum	<input type="checkbox"/> C45.0	Mesothelioma of pleura
<input type="checkbox"/> C18.1	Malignant neoplasm of appendix	<input type="checkbox"/> C45.1	Mesothelioma of peritoneum
<input type="checkbox"/> C18.2	Malignant neoplasm of ascending colon	<input type="checkbox"/> C48.1	Malignant neoplasm of specified parts of peritoneum
<input type="checkbox"/> C18.3	Malignant neoplasm of hepatic flexure	<input type="checkbox"/> C48.2	Malignant neoplasm of peritoneum, unspecified
<input type="checkbox"/> C18.4	Malignant neoplasm of transverse colon	<input type="checkbox"/> C34.00	Malignant neoplasm of unspecified main bronchus
<input type="checkbox"/> C18.5	Malignant neoplasm of splenic flexure	<input type="checkbox"/> C34.01	Malignant neoplasm of right main bronchus
<input type="checkbox"/> C18.6	Malignant neoplasm of descending colon	<input type="checkbox"/> C34.02	Malignant neoplasm of left main bronchus
<input type="checkbox"/> C18.7	Malignant neoplasm of sigmoid colon	<input type="checkbox"/> C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
<input type="checkbox"/> C18.8	Malignant neoplasm of overlapping sites of colon	<input type="checkbox"/> C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
<input type="checkbox"/> C18.9	Malignant neoplasm of colon, unspecified	<input type="checkbox"/> C48.8	Malignant neoplasm of overlapping retroperitoneum and peritoneum
<input type="checkbox"/> C19	Malignant neoplasm of rectosigmoid junction	<input type="checkbox"/> C54.0	Malignant neoplasm of isthmus uteri
<input type="checkbox"/> C20	Malignant neoplasm of rectum	<input type="checkbox"/> C54.1	Malignant neoplasm of endometrium
<input type="checkbox"/> C21.0	Malignant neoplasm of anus, unspecified	<input type="checkbox"/> C54.2	Malignant neoplasm of myometrium
<input type="checkbox"/> C21.1	Malignant neoplasm of anal canal	<input type="checkbox"/> C54.3	Malignant neoplasm of fundus uteri
<input type="checkbox"/> C21.2	Malignant neoplasm of cloacogenic zone	<input type="checkbox"/> C54.8	Malignant neoplasm of overlapping sites of corpus uteri
<input type="checkbox"/> C21.8	Malignant neoplasm of overlapping of rectum, anus and anal canal	<input type="checkbox"/> C54.9	Malignant neoplasm of corpus uteri, unspecified
<input type="checkbox"/> C33	Malignant neoplasm of trachea	<input type="checkbox"/> C55	Malignant neoplasm of uterus, part unspecified
<input type="checkbox"/> C34.12	Malignant neoplasm of upper lobe, left bronchus or lung	<input type="checkbox"/> C56.1	Malignant neoplasm of right ovary
<input type="checkbox"/> C34.2	Malignant neoplasm of middle lobe, bronchus or lung	<input type="checkbox"/> C56.2	Malignant neoplasm of left ovary
<input type="checkbox"/> C34.30	Malignant neoplasm of lower lobe, bronchus or lung	<input type="checkbox"/> C56.3	Malignant neoplasm of bilateral ovaries
<input type="checkbox"/> C34.31	Malignant neoplasm of lower lobe, right bronchus or lung	<input type="checkbox"/> C56.9	Malignant neoplasm of unspecified ovary
<input type="checkbox"/> C34.32	Malignant neoplasm of lower lobe, left bronchus or lung	<input type="checkbox"/> C57.00	Malignant neoplasm of unspecified fallopian tube
<input type="checkbox"/> C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung	<input type="checkbox"/> C57.01	Malignant neoplasm of right fallopian tube

Continued

<input type="checkbox"/> C57.02 Malignant neoplasm of left fallopian tube	<input type="checkbox"/> C93.12 Benign neoplasm of thyroid gland
<input type="checkbox"/> C57.10 Malignant neoplasm of unspecified broad ligament	<input type="checkbox"/> D44.0 Neoplasm of uncertain behavior of thyroid gland
<input type="checkbox"/> C57.11 Malignant neoplasm of right broad ligament	<input type="checkbox"/> D44.2 Neoplasm of uncertain behavior of parathyroid gland
<input type="checkbox"/> C57.12 Malignant neoplasm of left broad ligament	<input type="checkbox"/> D44.9 Neoplasm of uncertain behavior of unspecified endocrine gland
<input type="checkbox"/> C57.20 Malignant neoplasm of unspecified round ligament	<input type="checkbox"/> D46.0 Refractory anemia without ring sideroblasts, so stated
<input type="checkbox"/> C57.21 Malignant neoplasm of right round ligament	<input type="checkbox"/> D46.1 Refractory anemia with ring sideroblasts
<input type="checkbox"/> C57.22 Malignant neoplasm of left round ligament	<input type="checkbox"/> D46.20 Refractory anemia with excess of blasts, unspecified
<input type="checkbox"/> C57.3 Malignant neoplasm of parametrium	<input type="checkbox"/> D46.21 Refractory anemia with excess of blasts 1
<input type="checkbox"/> C57.4 Malignant neoplasm of uterine adnexa, unspecified	<input type="checkbox"/> D46.22 Refractory anemia with excess of blasts 2
<input type="checkbox"/> C92.00 Acute myeloblastic leukemia, not having achieved remission	<input type="checkbox"/> D46.4 Refractory anemia, unspecified
<input type="checkbox"/> C92.01 Acute myeloblastic leukemia, in remission	<input type="checkbox"/> D46.9 Myelodysplastic syndrome, unspecified
<input type="checkbox"/> C92.02 Acute myeloblastic leukemia, in relapse	<input type="checkbox"/> D46.A Refractory cytopenia with multilineage dysplasia
<input type="checkbox"/> C92.10 Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission	<input type="checkbox"/> D46.B Refractory cytopenia with multilineage dysplasia ring sideroblasts
<input type="checkbox"/> C92.11 Chronic myeloid leukemia, BCR/ABL-positive, in remission	<input type="checkbox"/> D46.C Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
<input type="checkbox"/> C92.12 Chronic myeloid leukemia, BCR/ABL-positive, in relapse	<input type="checkbox"/> D46.Z Other myelodysplastic syndromes
<input type="checkbox"/> C92.40 Acute promyelocytic leukemia, not having achieved remission	<input type="checkbox"/> E01.1 Iodine-deficiency related diffuse (endemic) goiter
<input type="checkbox"/> C92.41 Acute promyelocytic leukemia, in remission	<input type="checkbox"/> E01.0 Iodine-deficiency related multinodular (endemic) goiter
<input type="checkbox"/> C92.42 Acute promyelocytic leukemia, in relapse	<input type="checkbox"/> E01.2 Iodine-deficiency related (endemic) goiter, unspecified
<input type="checkbox"/> C92.50 Acute myelomonocytic leukemia, not having achieved remission	<input type="checkbox"/> E04.0 Nontoxic diffuse goiter
<input type="checkbox"/> C92.51 Acute myelomonocytic leukemia, in remission	<input type="checkbox"/> E04.1 Nontoxic single thyroid nodule
<input type="checkbox"/> C92.52 Acute myelomonocytic leukemia, in relapse	<input type="checkbox"/> E04. Nontoxic multinodular goiter
<input type="checkbox"/> C92.60 Acute myeloid leukemia with 11q23-abnormality not having achieved remission	<input type="checkbox"/> E04.8 Other specified nontoxic goiter
<input type="checkbox"/> C92.61 Acute myeloid leukemia with 11q23-abnormality in remission	<input type="checkbox"/> E04.9 Nontoxic goiter, unspecified
<input type="checkbox"/> C92.62 Acute myeloid leukemia with 11q23-abnormality in relapse	<input type="checkbox"/> Z85.030 Personal history of malignant carcinoid tumor of large intestine
<input type="checkbox"/> C92.A0 Acute myeloid leukemia with multilineage dysplasia, not having achieved remission	<input type="checkbox"/> Z85.038 Personal history of other malignant neoplasm of large intestine
<input type="checkbox"/> C92.A1 Acute myeloid leukemia with multilineage dysplasia, in remission	<input type="checkbox"/> Z85.040 Personal history of malignant carcinoid tumor of rectum
<input type="checkbox"/> D34 Acute myeloid leukemia with multilineage dysplasia, in relapse	<input type="checkbox"/> Z85.048 Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
<input type="checkbox"/> C92.A2 Chronic myelomonocytic leukemia not having achieved remission	
<input type="checkbox"/> C93.10 Chronic myelomonocytic leukemia, in remission	
<input type="checkbox"/> C93.11 Chronic myelomonocytic leukemia, in relapse	

Additional ICD10 Codes: _____

PATIENT CONSENT

REQUIRED

By signing this form, I acknowledge that the information provided by me is true and correct. I have read, or have had read to me, the Preventive Genomics Informed Consent document at the end of this test requisition form and understand the information regarding molecular genetics testing. For direct insurance billing: I authorize my insurance benefits to be paid directly to Preventive Genomics and their affiliates. I authorize Preventive Genomics to release medical information concerning my testing to my insurer, to act as my designated representative for the purpose of appealing any denial of benefits as needed, and to request additional medical records for this purpose. I understand that I am financially responsible for any amounts not covered by my insurer and responsible for sending Preventive Genomics and their affiliates any money received from my health insurance company. I also give permission for my specimen and clinical information to be used in de-identified studies at Preventive Genomics and their affiliates for publication, if appropriate. I have had the opportunity to ask questions about the testing, the procedure, the risks, and the alternatives. I authorize Preventive Genomics and their affiliates to perform the testing as ordered

Signature

Date

CERTIFICATE OF MEDICAL NECESSITY, CONSENT, TEST AUTHORIZATION AND PHYSICIAN SIGNATURE

REQUIRED

The individual signing this form, or their representative, hereby confirms their status as a licensed medical professional authorized to order genetic testing and confirms that the patient has provided informed consent for the testing and that it is medically necessary. They certify that any custom panel and/or ordered test(s) requested on this test requisition form are reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome, or disorder. They acknowledge that the test results may have an impact on the patient's medical management. The information provided on this form is accurate to the best of their knowledge. The signature on this form applies to the attached letter of medical necessity. If the insurance provider requests the laboratory to gather the medical necessity for any reason, the signer agrees to provide the Care Plan notes and Letter of Intent for this order.

Signature

Date

INFORMED CONSENT

For the purposes of this consent, “I”, “my”, and “your” will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST

The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or pass on a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?

1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.
2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.
3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.
4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes.

We may disclose this information to the ordering healthcare provider if it likely affects medical care.

Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information Preventive Genomics used to interpret my results. Healthcare providers can contact Preventive Genomics at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as “trio tests” since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that Preventive Genomics will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information about a relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING

RISKS AND LIMITATIONS OF GENETIC TESTING

1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.
2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.
3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.
4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.
5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary. To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

INTERNATIONAL SAMPLES

If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION

After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. Preventive Genomics will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made.

I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and Preventive Genomics will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. Preventive Genomics will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION

De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this deidentified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. Preventive Genomics shares this type of information with healthcare providers, scientists, and healthcare databases. Preventive Genomics will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. Preventive Genomics believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

- Applicable only for full exome sequencing and genome sequencing tests
- Does not pertain to Xpanded® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called “incidental” or “secondary” and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

WHAT WILL BE REPORTED FOR THE PATIENT?

All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

WHAT WILL BE REPORTED FOR RELATIVES?

The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS

Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified nor reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE

For insurance billing, I understand and authorize Preventive Genomics to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to Preventive Genomics.

I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Preventive Genomics as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by Preventive Genomics on my behalf, I agree to endorse the insurance check and forward it to Preventive Genomics within 30 days of receipt as payment towards Preventive Genomics claim for services rendered.

If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Preventive Genomics. I further understand and agree that, if I fail to make payment for genetic testing, in accordance with the payment policies of Preventive Genomics, my account may be turned over to an external collection agency for non-payment. I agree to pay any associated collection costs, including attorney fees. By my signature on the Preventive Genomics Test Requisition Form or at the bottom of this form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider.