


<div><div>PREVENTIVE genomics</div></div>		CLIA ID: 45D2332030 Lab Director: Dr. Congying Gu		DIABETES MODY & DIABETES PREDICT TESTING REQUISITION FORM		
INSTRUCTIONS			ORDERING PHYSICIAN INFORMATION			
<div><div></div><div>■ Patient and Physician must sign the consent form</div><div>■ All items identified as 'Required' must be Provided/attached to the requisition form.</div></div>			Physician Name		NPI#	FAX#
			Office/Practice/Institution Name		Physician's Email	
			Street Address			
SUBMISSION CHECKLIST			City		State	Zip Code
<div><div></div> SOAP notes and progress notes</div> <div><div></div> Patient insurance ID card or face sheet</div> <div><div></div> Physician and Patient Signature</div>						

FAMILY HISTORY					
Diabetic Father's Father? <input type="checkbox"/>	Diabetic Father's Mother? <input type="checkbox"/>	Diabetic Mother's Father? <input type="checkbox"/>	Diabetic Mother's Mother? <input type="checkbox"/>	Total Number of Siblings: Number of Siblings with Diabetes:	Total Number of Children: Number of Children with Diabetes:
Diabetic Father? <input type="checkbox"/> Age at Diagnosis?.....		Diabetic Mother? <input type="checkbox"/> Age at Diagnosis?.....		Please add the age of diagnosis for Siblings with Diabetes: Sibling1:..... Sibling3:..... Sibling2:..... Sibling4:.....	Please add the age of diagnosis for Children with Diabetes: Sibling1:..... Sibling3:..... Sibling2:..... Sibling4:.....
Family History of Renal Disease (Cysts, Proteinuria, Renal Failure, Renal Dysplasia, Renal agenesis? If Yes, Please add to Family History details:				Family History of Deafness? If Yes, Please add to Family History details:	

QUESTIONNAIRE	
<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Family History</div> <p>Does the patient have a family history of diabetes in at least three consecutive generations (grandparents, parents, siblings)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are there any known cases of early-onset diabetes (before age 25) in the patient's family?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p>	<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Age of Onset</div> <p>Did the patient develop diabetes before the age of 25?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Did any family members develop diabetes before the age of 25?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Phenotype</div> <p>Is the patient non-obese at the time of diabetes diagnosis?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are there family members who were non-obese at the time of their diabetes diagnosis? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the patient present with atypical diabetes features that do not fit the classic Type 1 or Type 2 diabetes profiles?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p>	<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Insulin Independence</div> <p>Is the patient able to control blood glucose levels without the need for insulin for at least five years after diagnosis? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are there any family members with diabetes who manage their condition without insulin for an extended period after diagnosis?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Clinical Presentation</div> <p>Does the patient have any unusual clinical features or complications that might suggest a genetic form of diabetes?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p> <p>Are there family members with diabetes who have presented with similar unusual clinical features?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p>	<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Genetic Mutations</div> <p>Has there been any previous genetic testing indicating mutations in MODY-associated genes (e.g., HNF1A, HNF4A, GCK)?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p> <p>Are there family members who have been diagnosed with MODY through genetic testing?</p> <p><input type="checkbox"/> Yes, please specify _____</p> <p><input type="checkbox"/> No</p>
	<div style="background-color: #008080; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Previous Genetic Testing</div> <p>Has the patient undergone genetic counseling or previous genetic testing related to diabetes?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Have any family members undergone genetic counseling or testing indicating a predisposition to MODY?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

TEST PANELS		
Test name	Genes	Test Information
Diabetes MODY (Maturity Onset Diabetes of the Young)	30-Gene Panel (see below for more information)	Identifies genetic mutations associated with MODY, a form of diabetes characterized by an autosomal dominant inheritance pattern and typically diagnosed in adolescence or early adulthood.
Diabetes Predict	16-Gene Panel (see below for more information)	Assesses genetic risk for developing Type 2 diabetes.

Targeted Single Gene Testing Panel (Select the genes below) ☐ or Diabetes MODY (Tests All Genes) ☐

<input type="checkbox"/> ABCC8	<input type="checkbox"/> GATA6	<input type="checkbox"/> HNF1A	<input type="checkbox"/> KCNJ11	<input type="checkbox"/> PDX1	<input type="checkbox"/> SLC2A2
<input type="checkbox"/> BLK	<input type="checkbox"/> GCK	<input type="checkbox"/> HNF1B	<input type="checkbox"/> KLF11	<input type="checkbox"/> PPARG	<input type="checkbox"/> TCF7L2
<input type="checkbox"/> CAPN10	<input type="checkbox"/> GLIS3	<input type="checkbox"/> HNF4A	<input type="checkbox"/> NEUROD1	<input type="checkbox"/> PRF1A	<input type="checkbox"/> UCP2
<input type="checkbox"/> EIF2AK3	<input type="checkbox"/> GLUD1	<input type="checkbox"/> INS	<input type="checkbox"/> NEUROD3	<input type="checkbox"/> RFX6	<input type="checkbox"/> WFS1
<input type="checkbox"/> FOXP3	<input type="checkbox"/> HADH	<input type="checkbox"/> INSR	<input type="checkbox"/> PAX4	<input type="checkbox"/> ALC16A1	<input type="checkbox"/> ZFP57

☐ DIABETES PREDICT TESTING PANEL

SLC16A11, INS-IGF2, HNF1A, WFS1, SLC30A8, PPARG, IGF2BP2, ADCY5, JAZF1, CDKAL1, HHEX/IDE, KCNJ11, KCNQ1, TCF7L2, FTO, CDKN2A/B

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.

Type 2 Diabetes ICD10 codes

Hyperosmolarity

- ☐ E11.0: Type 2 diabetes mellitus with hyperosmolarity
- ☐ E11.00: Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic hyperosmolar coma (NKHHC)
- ☐ E11.01: Type 2 diabetes mellitus with hyperosmolarity with coma

Ketoacidosis

- ☐ E11.1: 2 diabetes mellitus with ketoacidosis
- ☐ E11.10: Type 2 diabetes mellitus with ketoacidosis without coma
- ☐ E11.11: Type 2 diabetes mellitus with ketoacidosis with coma

Kidney Complications

- ☐ E11.2: Type 2 diabetes mellitus with kidney complications
- ☐ E11.21: Type 2 diabetes mellitus with diabetic nephropathy
- ☐ E11.22: Type 2 diabetes mellitus with diabetic chronic kidney disease
- ☐ E11.29: Type 2 diabetes mellitus with other diabetic kidney complication

Ophthalmic Complications

- ☐ E11.3: Type 2 diabetes mellitus with ophthalmic complications
- ☐ E11.31: Type 2 diabetes mellitus with unspecified diabetic retinopathy
- ☐ E11.311: Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
- ☐ E11.319: Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
- ☐ E11.32: Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy
- ☐ E11.321: Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
- ☐ E11.329: Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
- ☐ E11.33: Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy
- ☐ E11.331: Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
- ☐ E11.339: Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
- ☐ E11.34: Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy
- ☐ E11.341: Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
- ☐ E11.349: Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
- ☐ E11.35: Type 2 diabetes mellitus with proliferative diabetic retinopathy
- ☐ E11.351: Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
- ☐ E11.359: Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
- ☐ E11.36: Type 2 diabetes mellitus with diabetic cataract
- ☐ E11.39: Type 2 diabetes mellitus with other diabetic ophthalmic complication

Neurological Complications

- ☐ E11.4: Type 2 diabetes mellitus with neurological complications
- ☐ E11.40: Type 2 diabetes mellitus with diabetic neuropathy, unspecified
- ☐ E11.41: Type 2 diabetes mellitus with diabetic mononeuropathy
- ☐ E11.42: Type 2 diabetes mellitus with diabetic polyneuropathy
- ☐ E11.43: Type 2 diabetes mellitus with diabetic autonomic (poly) neuropathy
- ☐ E11.44: Type 2 diabetes mellitus with diabetic amyotrophy
- ☐ E11.49: Type 2 diabetes mellitus with other diabetic neurological complication

Circulatory Complications

- ☐ E11.5: Type 2 diabetes mellitus with circulatory complications
- ☐ E11.51: Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
- ☐ E11.52: Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
- ☐ E11.59: Type 2 diabetes mellitus with other circulatory complications

Other Specified Complications

- ☐ E11.6: Type 2 diabetes mellitus with other specified complications
- ☐ E11.610: Type 2 diabetes mellitus with diabetic neuropathic arthropathy
- ☐ E11.618: Type 2 diabetes mellitus with other diabetic arthropathy
- ☐ E11.620: Type 2 diabetes mellitus with diabetic dermatitis
- ☐ E11.621: Type 2 diabetes mellitus with foot ulcer
- ☐ E11.622: Type 2 diabetes mellitus with other skin ulcer
- ☐ E11.628: Type 2 diabetes mellitus with other skin complication
- ☐ E11.63: Type 2 diabetes mellitus with periodontal disease
- ☐ E11.638: Type 2 diabetes mellitus with other oral complications
- ☐ E11.64: Type 2 diabetes mellitus with hypoglycemia
- ☐ E11.641: Type 2 diabetes mellitus with hypoglycemia with coma
- ☐ E11.649: Type 2 diabetes mellitus with hypoglycemia without coma
- ☐ E11.65: Type 2 diabetes mellitus with hyperglycemia
- ☐ E11.69: Type 2 diabetes mellitus with other specified complication

Unspecified Complications

- ☐ E11.8: Type 2 diabetes mellitus with unspecified complications
- ☐ E11.9: Type 2 diabetes mellitus without complications

Hyperlipidemia ICD10 Codes

- ☐ E78.0: Pure hypercholesterolemia
- ☐ E78.1: Pure hyperglyceridemia
- ☐ E78.2: Mixed hyperlipidemia
- ☐ E78.3: Hyperchylomicronemia
- ☐ E78.4: Other hyperlipidemia
- ☐ E78.5: Hyperlipidemia, unspecified

Hypothyroidism ICD10 Codes

- ☐ 1. E03.0: Congenital hypothyroidism with diffuse goiter
- ☐ 2. E03.1: Congenital hypothyroidism without goiter
- ☐ 3. E03.2: Hypothyroidism due to medications and other exogenous substances
- ☐ 4. E03.3: Postinfectious hypothyroidism
- ☐ 5. E03.4: Atrophy of thyroid (acquired)
- ☐ 6. E03.5: Myxedema coma
- ☐ 7. E03.8: Other specified hypothyroidism
- ☐ 8. E03.9: Hypothyroidism, unspecified
- ☐ E13.9: Other specified diabetes mellitus without complications
- ☐ E13.65: Other specified diabetes mellitus with hyperglycemia

Unspecified Complications

- ☐ E08.649: Diabetes mellitus due to underlying condition with hypoglycemia without coma
- ☐ E09.64: Drug or chemical induced diabetes mellitus with hypoglycemia

Unspecified Complications

- ☐ E10.8: Type 1 diabetes mellitus with unspecified complications
- ☐ E10.9: Type 1 diabetes mellitus without complications

Type 1 Diabetes ICD10 codes

Hyperosmolarity

- ☐ E10.0: Type 1 diabetes mellitus with hyperosmolarity
- ☐ E10.00: Type 1 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic hyperosmolar coma (NKHHC)
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- ☐ E10.321: Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema

- ☐ E10.329: Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema

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- ☐ E10.331: Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema

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- ☐ E10.349: Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema

- ☐ E10.35: Type 1 diabetes mellitus with proliferative diabetic retinopathy
- ☐ E10.351: Type 1 diabetes mellitus with proliferative diabetic retinopathy

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- ☐ E10.36: Type 1 diabetes mellitus with diabetic cataract

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- ☐ E10.44: Type 1 diabetes mellitus with diabetic amyotrophy
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- ☐ E10.69: Type 1 diabetes mellitus with other specified complication

BMI ICD10 Codes

- | | |
|----------------------------------|--|
| <input type="checkbox"/> Z68.1: | Body mass index (BMI) 19 or less, adult |
| <input type="checkbox"/> Z68.20: | Body mass index (BMI) 20.020.9, adult |
| <input type="checkbox"/> Z68.21: | Body mass index (BMI) 21.021.9, adult |
| <input type="checkbox"/> Z68.22: | Body mass index (BMI) 22.022.9, adult |
| <input type="checkbox"/> Z68.23: | Body mass index (BMI) 23.023.9, adult |
| <input type="checkbox"/> Z68.24: | Body mass index (BMI) 24.024.9, adult |
| <input type="checkbox"/> Z68.25: | Body mass index (BMI) 25.025.9, adult |
| <input type="checkbox"/> Z68.26: | Body mass index (BMI) 26.026.9, adult |
| <input type="checkbox"/> Z68.27: | Body mass index (BMI) 27.027.9, adult |
| <input type="checkbox"/> Z68.28: | Body mass index (BMI) 28.028.9, adult |
| <input type="checkbox"/> Z68.29: | Body mass index (BMI) 29.029.9, adult |
| <input type="checkbox"/> Z68.30: | Body mass index (BMI) 30.030.9, adult |
| <input type="checkbox"/> Z68.31: | Body mass index (BMI) 31.031.9, adult |
| <input type="checkbox"/> Z68.32: | Body mass index (BMI) 32.032.9, adult |
| <input type="checkbox"/> Z68.33: | Body mass index (BMI) 33.033.9, adult |
| <input type="checkbox"/> Z68.34: | Body mass index (BMI) 34.034.9, adult |
| <input type="checkbox"/> Z68.35: | Body mass index (BMI) 35.035.9, adult |
| <input type="checkbox"/> Z68.36: | Body mass index (BMI) 36.036.9, adult |
| <input type="checkbox"/> Z68.37: | Body mass index (BMI) 37.037.9, adult |
| <input type="checkbox"/> Z68.38: | Body mass index (BMI) 38.038.9, adult |
| <input type="checkbox"/> Z68.39: | Body mass index (BMI) 39.039.9, adult |
| <input type="checkbox"/> Z68.41: | Body mass index (BMI) 40.044.9, adult |
| <input type="checkbox"/> Z68.42: | Body mass index (BMI) 45.049.9, adult |
| <input type="checkbox"/> Z68.43: | Body mass index (BMI) 50.059.9, adult |
| <input type="checkbox"/> Z68.44: | Body mass index (BMI) 60.069.9, adult |
| <input type="checkbox"/> Z68.45: | Body mass index (BMI) 70 or greater, adult |

Additional ICD Codes:

PATIENT CONSENT REQUIRED

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
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Date _____

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

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
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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.