PREVENTION GENETICS

DISEASE PREVENTION THROUGH GENETIC TESTING

Office use only

3800 S. Business Park Ave
Marshfield, WI 54449
Phone: 715-387-0484
Fax: 715-384-3661

Targeted Variant Test Requisition Form

(12/30/16)

- Testing must be ordered by a qualified healthcare provider.
- See "Test Selection" for details about free VUS testing and for recommendations about submitting positive control samples.
- MCC studies offered at no additional charge for any fetal testing.
- Test information is available at www.preventiongenetics.com.

Person Completing Form	*Contact Information (phone or email)*	*Date of Request*

Patient Information

Patient's Last (Family) Name	*First Name*	*MI*	*Date of Birth:* Month Day Year

Patient ID Code	*Date Collected:* Month Day Year	*Sex:* ☐ Male ☐ Female ☐ Other *Karyotype:*

Specimen Source:
☐ *Whole blood* ☐ *Extracted DNA Source:* ☐ *Cultured Cells Source:* ☐ *Tissue Source:* ☐ *Direct Amnio* ☐ *Direct CVS* ☐ *Other:*

Reason for test	*GeoAncestry/Ethnicity*	*Has patient's relative been tested at PreventionGenetics?*	*Relationship to proband:*	*Ongoing pregnancy?*
☐ Diagnosis ☐ Presymptomatic/ At risk ☐ Carrier Testing		☐ Yes ☐ No *If yes, provide name & DOB:*	☐ *Mother* ☐ *Sibling* ☐ *Father* ☐ *Child* ☐ *Other:*	☐ Yes ☐ No Prenatal Healthcare Statement required for fetal testing.

Has patient had a blood transfusion within the last month?	*Has patient had a bone marrow transplant?*	*Other relevant clinical information (Labs, biopsies, other genetic testing performed, etc). Please attach pedigree if possible.*
☐ Yes ☐ No *If yes, provide type & date:*	☐ Yes ☐ No	

Test Selection

Free testing for variants of unknown significance (VUS) may be offered in up to two family members of probands who were tested at PreventionGenetics. Free testing for deletion/duplications of unknown significance discovered by aCGH will be available for family members of the proband only if we are able to test the del/dup by PCR or MLPA.

If the family member was tested at an outside laboratory, we recommend that you submit the outside report and a specimen from that individual to serve as a positive control. The positive control specimen will be tested free of charge and no report will be provided. If a positive control is not provided, negative results will carry a limitation stating that PreventionGenetics did not have the opportunity to verify that we can detect the variant in this family.

**Test Code 1400 is only available for family members of probands who were tested at PreventionGenetics and if we confirmed the del/dup by PCR.*

Test Code	*Gene(s):*	*Variant(s):*
☐ ***100*** *(1 variant)* ☐ ***200*** *(2 variants)* ☐ ***300*** *(3 variants)* ☐ ***1400*** *(Known familial del/dup, PCR)** ☐ ***600*** *(Del/dup via aCGH)* ☐ ***800*** *(Maternal Cell Contamination)* ☐ ***990*** *(Prenatal variants)*		

Special Instructions:
☐ ***NO CHARGE*** *(Meets Variant Follow Up Policy or Included in Test 990)*
☐ ***NO CHARGE/ NO REPORT*** *(Positive Control Only)*
☐ ***STAT REQUEST*** *(Add 25% surcharge (except Test 990)*
☐ ***HOLD TESTING*** *(pending MOH approval, insurance preauth, etc.)*

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Provider/Laboratory Contact Information

- **Our preferred method of report transmission is secure email (via ZixCorp). Please provide an email address when possible.**
- **If you have additional specific reporting requests, please indicate them below.**

Provider Information			
Institution			
Address (please include city, state, country & postal code)			
Requesting Physician (First, Last, Degree)		***Requesting Genetic Counselor (First, Last, Degree)***	
Phone Number	***NPI#:***	***Phone Number***	***NPI#***
Email		***Email***	
Test Reporting Instructions *Our preferred method of report transmission is email (via ZixCorp)*		**Test Reporting Instructions** *Our preferred method of report transmission is email (via ZixCorp)*	
Secure Email (via ZixCorp): ☐ *use above*		***Secure Email (via ZixCorp):*** ☐ *use above*	
☐ ***DO NOT use ZixCorp. Instead, send email via ShareFile.***		☐ ***DO NOT use ZixCorp. Instead, send email via ShareFile.***	
☐ ***DO NOT email results. Instead, send via fax (provide fax #):***		☐ ***DO NOT email results. Instead, send via fax (provide fax #):***	

Sendout Laboratory (Complete only if report needed)	**Other**
Laboratory & Contact Person	***Contact Name***
Address	***Address***
Phone Number	***Phone Number***
Email	***Email***
Test Reporting Instructions *Our preferred method of report transmission is email (via ZixCorp)*	**Test Reporting Instructions** *Our preferred method of report transmission is email (via ZixCorp)*
Secure Email (via ZixCorp): ☐ *use above*	***Secure Email (via ZixCorp):*** ☐ *use above*
☐ ***DO NOT use ZixCorp. Instead, send email via ShareFile.***	☐ ***DO NOT use ZixCorp. Instead, send email via ShareFile.***
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Billing Instructions

1. Please choose one of the three billing options:

- ☐ Institutional
- ☐ Individual
- ☐ Insurance

2. Provide all information for the selected option only

Note: Patient testing will be delayed until all of the billing requirements have been met. Please print clearly. If Individual/Insurance billing information is incomplete, the Institution will be billed. Tests that are cancelled while in progress will be billed for the amount of work completed up to that point. If the patient's specimen is collected in New York, a New York State Non-Permitted Laboratory Test Request approval letter (see web site) must be included before testing will proceed.

1. Institutional Billing (Preferred)

Billing Institution		***PO Number***
Contact	***Phone Number(s)***	***Email***
Address		
City	***State***	***Zip***
Email Invoice **Email Address:**	***Copy of Test Report(s) for Billing*** ☐ **Secure Email (via ZixCorp):** ☐ **Other (please specify):**	

2. Individual Billing

Responsible Party's Name (Must be 18 years or older)	***Phone Number(s)***	***Email***
Address		
City	***State***	***Zip***

ACCEPTANCE OF FINANCIAL RESPONSIBILITY FOR GENETIC TESTING

Note: PreventionGenetics cannot proceed with testing of the specimen without a signature below.

My signature below indicates that I accept financial responsibility for all fees associated with this genetic testing order.

_____	_____	_____
Signature of Responsible Party	***Printed Name of Responsible Party***	***Date***

COMPLETE THE FOLLOWING FOR CREDIT CARD PAYMENT

Credit Card # / (VISA, Discover, or Mastercard only)	***Expiration Date***	***3-Digit Security Code***

My signature below authorizes PreventionGenetics to charge my credit card for services for which I am responsible.

Signature: ***Date:***

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Billing Instructions

3. Insurance Billing

We will file an insurance claim on behalf of the patient with any commercial insurance company. However, the claim will be submitted as an "out of network" service provider. We are in network (contracted provider) with a limited number of insurance plans (see website). The patient is responsible for any portion of the test fee not covered by the insurance company for any reason including, but not limited to, co-payments, co-insurance, unmet deductibles, or non-covered services.

Responsible Party's Name (Must be 18)	*Phone Number(s)*	*Email*

Responsible Party Address

City *State* *Zip*

Policyholder Name (Required)	*Please indicate the type of insurance: (Circle One)* *Private / Medicare / WI Medicaid** **We only accept WI Medicaid*	*Primary Insurance Company Name (Required)*

Insurance Company Address- Claims

City *State* *Zip*

ICD-10 Codes (Required)	*Policy ID#*	*Group #*	*Authorization #*

Please attach the following:

Note: PreventionGenetics cannot proceed with testing of the specimen until all information is received.

- ☐ ***NPI # of Requesting Physician _____***
- ☐ ***Medicare – signed ABN Form completed IN FULL***
- ☐ ***Copy of both sides of Insurance Card***
- ☐ ***Authorization number or letter of agreement from insurance company (if available). If not included, we will routinely perform pre-verification prior to initiating testing & will relay information to ordering provider.***
- ☐ ***Letter of Medical Necessity***
- ☐ ***Relevant Medical Records***
- ☐ ***NY Non-permitted lab approval letter (if specimen collected in NY)***
- ☐ ***Share results of benefits investigation with patient directly via email provided above or FAX# _____***

AUTHORIZATION TO ASSIGN BENEFITS AND ACCEPT FINANCIAL RESPONSIBILITY FOR MY ACCOUNT

Note: PreventionGenetics cannot proceed with testing of the specimen without a signature below.

I authorize PreventionGenetics to release information received including, without limitation, medical information, which includes laboratory test results, such as genetic tests results, to my health plan/insurance carrier and its authorized representatives. I further authorize insurance payments directly to PreventionGenetics for the services rendered. I understand my health plan/insurance/Medicare/Medicaid carrier may not approve and reimburse my medical genetic services in full due to usual and customary rate limits, benefit exclusions, coverage limits, lack of authorization, medical necessity or otherwise. I understand I am financially responsible for fees not paid in full by my insurer, co-payments, and policy deductibles except where my liability is limited by contract or State and Federal law. I agree to help PreventionGenetics resolve any insurance claim issues.

_____ _____ _____

Signature of Patient or Guardian ***Printed Name of Patient or Guardian*** ***Date***

Credit Card # / (VISA, Discover, or Mastercard only)	*Expiration Date*	*3- Digit Security Code*

My signature below authorizes PreventionGenetics to charge my credit card for services for which I am responsible upon completion of insurance processing.

Signature: ***Date:***

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Specimen Requirements

Below you will find our preferred specimen types by methodology and turnaround times (TAT).
STAT TAT (8-10 calendar days) available for 25% surcharge for Sanger sequencing. Cannot be guaranteed for aCGH.

General Specimen Requirements (For extracted DNA and other acceptable types, see specific test heading below)

WHOLE BLOOD: Collect 3-5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants.

SALIVA: Oragene™ Saliva Collection kit used according to manufacturer instructions.
**Saliva is not accepted for MLPA tests (except Test Code 1941 only).

FETAL (CVS/AMNIOCYTES) AND OTHER CELL CULTURE: Culture and send at least two, T-25 flasks of confluent cells. For full gene Sanger sequencing, two to four flasks per gene tested is preferred (dependent on size of gene). For NGS panels, two flasks are often sufficient; however, some panels may require additional flasks. We recommend maintaining a local back-up culture. Please contact us for additional details.
**CVS and amniocytes not accepted for gene-centric aCGH or MLPA tests at this time; acceptable for CMA for non-ongoing pregnancies only at this time.

FRESH, FROZEN TISSUE: Collect 2mm x 2mm x 2mm tissue and flash freeze. Tissue to be sent frozen (preferably dry ice). Please contact us for additional details.

Prenatal Targeted Testing (Test Code 990 only)
DIRECT AMNIOTIC FLUID/CHORIONIC VILLI: Collect 10-15 ml of direct amniotic fluid or 5-10 mg cleaned CVS tissue (~15-20 cleaned villi). We recommend maintaining a local back-up culture.

Next-Gen Sequencing (Great majority of tests completed within 28 days.)

DNA: Send in screw cap tube at least 10 µg of purified DNA at a concentration of at least 50 µg/ml (indicate concentration on tube label).

Sanger Sequencing (Great majority of tests completed within 18 days. Multiple genes are run sequentially unless concurrent testing is marked; great majority of Sanger panels are completed within 2-4 weeks.)*

DNA: Send in screw cap tube at least 15 µg of purified DNA at a concentration of at least 20 µg/ml (indicate concentration on tube label). For tests involving the sequencing of more than three genes, send an additional 5 µg DNA per gene.

SEMEN: Collect 1-2 vials and flash frozen. Vials to be sent frozen (preferably on dry ice). Please contact us for details.

Deletion/Duplication via aCGH & MLPA (Great majority of del/dup tests via aCGH are completed within 28 days; great majority of MLPA tests are completed within 20 days.)*

DNA: Send in screw cap tube at least 1 µg of purified DNA at a concentration of at least 100 µg/ml (indicate concentration on tube label). We cannot accept DNA extracted from cultured cells.
**DNA extracted from Saliva, CVS, and amniocytes not accepted for gene-centric aCGH or MLPA at this time.

Whole-Genome Chromosomal Microarray (Great majority of tests are completed within 20 days.)

DNA: Collect at least 5 µg of DNA in TE (10 mM Tris-cl pH 8.0, 1mM EDTA), dissolved in 200 µl at a concentration of at least 100 ng/ul (indicate concentration on tube label). DNA extracted using a column-based method (Qiagen) or bead-based technology is preferred.
**DNA extracted from CVS and amniocytes acceptable for CMA for non-ongoing pregnancies only at this time.

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Shipping Instructions & Additional Information

Shipping/Handling Instructions

Please label all specimen containers with the patient's name, date of birth and/or ID number. At least two identifiers should be listed on specimen containers. We accept specimen deliveries Monday-Saturday for all specimen types except cell cultures, direct amniotic fluid, or direct chorionic villi. Cell culture deliveries are routinely accepted Monday-Thursday and require advance notice of arrival. If a Friday or Saturday delivery is necessary, please contact us to make arrangements. Saturday delivery should especially be avoided when possible as prenatal specimens are not processed over the weekend. Holiday schedules will be posted on our home page at least one week prior to major holidays.

BLOOD: Do not freeze. During hot weather, include a frozen ice pack in the shipping container. Place a paper towel or other thin material between the ice pack and the blood tube. In cold weather include an unfrozen ice pack in the shipping container as insulation. At room temperature, blood specimen is stable for up to 48 hours. If refrigerated, blood specimen is stable for up to one week.

DNA: DNA may be shipped at room temperature. Label the tube with the composition of the solute, DNA concentration as well as the patient's name, date of birth, and/or ID number. We only accept genomic DNA for testing. We do NOT accept products of whole genome amplification reactions or other amplification reactions.

CELL CULTURES & DIRECT AF/CVS: We are NOT able to culture cells. Send specimens in insulated, shatterproof container overnight. Cell cultures may be shipped at room temperature or refrigerated.

Address	Testing Kits
Diagnostic Lab PreventionGenetics 3800 S. Business Park Ave. Marshfield, WI 54449 USA	Clinical testing kits with prepaid return shipping are now available for our U.S. clients. We are able to provide Clinical Testing Kits to our international clients without the return postage at this time. To order kits, submit requests through our Electronic Order Form on our web site or contact our Client Service Representatives at 715-387-0484, ext. 0.

Prenatal Testing

Please sign Prenatal Healthcare Provider Statement and contact us in advance regarding prenatal test requests.

DNA Genotyping Panel

For quality control purposes, the PreventionGenetics DNA Genotyping Panel is performed on all clinical specimens. Genotyping results are ***not*** included in test reports.

DNA Banking

DNA Banking has a reduced price of $98 for patients if clinical testing is also being performed with us. For DNA Banking, see our DNA Banking Process and DNA Banking Forms. For questions related to DNA Banking, contact our DNA Banking Director at 715-387-0484, ext. 151 or email dnabanking@preventiongenetics.com.

Contact Us

For additional questions or concerns, please contact our Client Service Representatives at 715-387-0484, ext. 0 or our Genetic Counseling Team at ext. 208 or clinicaldnatesting@preventiongenetics.com.