

PRENATAL TESTING GUIDELINES AND TEST REQUISITION FORM

PreventionGenetics should be notified in advance of arrival of a prenatal specimen. For all prenatal testing in ongoing pregnancies, we require a signature from the health care provider on our "PRENATAL HEALTH CARE PROVIDER'S STATEMENT," which is included on page 2. We expect that the ordering provider will take responsibility for the appropriateness of the requested testing.

We accept fetal DNA, fetal tissue, cultured fetal cells, or direct CVS / amniotic fluid. However, acceptable specimen type is dependent on the fetal testing requested (see page 7 for more information). Retention of a backup culture of the fetal cells is strongly recommended. Where possible, please ship cultured cells so that they will arrive at PreventionGenetics no later than Thursday in the work week. PreventionGenetics now offers cell culture (see below for details).

We require at least one parental specimen be sent as part of prenatal testing for QA purposes.

Maternal cell contamination (MCC) of fetal sample will be tested using the PreventionGenetics DNA Genotyping Panel. Even in cases of autosomal dominant disorders in which the father has the causative variant, blood or DNA from the mother is strongly encouraged to be sent for the MCC test. We do not charge extra for MCC studies for any fetal testing, but the CPT Code, 81265, will be included on invoices and insurance claims as appropriate.

At this time, PreventionGenetics is not validated to offer prenatal testing for MLPA or most repeat expansion testing. We also do not currently offer whole exome sequencing (WES) for ongoing pregnancies. PreventionGenetics does not perform prenatal testing for sex. We will also not report fetal sex unless this is critical for interpretation of test results. PreventionGenetics does not perform pre-implantation DNA testing.

FAMILIAL VARIANT TESTING TEST CODE 990, \$990

Familial variants must be known in advance from testing of parents, affected siblings or other relatives. These variants must be confirmed at PreventionGenetics in the parents and/or proband. Parental specimens

may be sent in advance of the prenatal specimen. Additional CPT codes for parental and MCC testing may be included at time of invoicing. We require at least one parental specimen be sent for all targeted prenatal testing requests. **Turnaround Time:** 8-10 calendar days from receipt of specimen and signed PROVIDER'S STATEMENT.

NEXTGEN SEQUENCING FOR ONGOING PREGNANCY

see standard prices listed on our website

We will perform NextGen tests for ongoing pregnancies. **Turnaround Time:** The great majority of NGS tests are completed within 28 days from date of specimen and signed PROVIDER'S STATEMENT receipt. Our formal STAT option is not available. We will courtesy prioritize requests related to ongoing pregnancies.

FULL GENE SANGER SEQUENCING FOR ONGOING PREGNANCY

see standard prices listed on our website

We will perform full gene Sanger sequencing tests for ongoing pregnancies. **Turnaround Time:** The great majority of Sanger tests are completed within 18 days from date of specimen and signed PROVIDER'S STATEMENT receipt for a single gene. Our STAT option is available for a 25% additional charge. The great majority of STAT requests are completed within eight calendar days. If we are unable to complete STAT requests within 10 days, the surcharge will be waived. We will courtesy prioritize requests related to ongoing pregnancies.

DELETION / DUPLICATION ANALYSIS VIA GENE-CENTRIC aCGH TEST

see standard prices listed on our website

We will perform gene-centric aCGH for prenatal specimens. See our full Test Description for details and limitations. At this time MLPA is not validated for prenatal specimen types. If a copy number variation (CNV) was identified via gene-centric aCGH and was confirmed by PCR in the proband, the PCR-based test is an option for a subsequent pregnancy only when the father

is a carrier of the CNV. When the mother is a carrier, prenatal testing must be performed by aCGH due to the possibility that even a low level of maternal cell contamination may affect the interpretation of a PCR-based test. Please contact our genetic counseling team to discuss any familial CNV situations. **Turnaround Time:** The great majority of gene-centric aCGH tests are completed within 14 days from date of specimen and signed PROVIDER'S STATEMENT receipt. Our STAT option is available for a 25% additional charge. The great majority of STAT requests are completed within eight calendar days. If we are unable to complete STAT requests within 10 days, the surcharge will be waived. We will courtesy prioritize requests related to ongoing pregnancies.

DELETION / DUPLICATION ANALYSIS VIA CHROMOSOMAL MICROARRAY VIA ACGH AND SNP TEST

see Del/Dup Array Tests

We will perform Rapid Prenatal Chromosomal Microarray (Test Code 3780, \$1390) or Whole Genome Chromosomal Microarray - Prenatal (Test Code 2200, \$1390). See our full Test Descriptions for details and limitations. Maternal cell specimen is required. For Rapid Prenatal CMA, please use Prenatal Rapid CMA Test Requisition Form.

TESTING IN CASES OF FETAL DEMISE OR PREGNANCY TERMINATION

see standard prices listed on our website

In the case of fetal demise or pregnancy termination, no "PRENATAL HEALTH CARE PROVIDER'S STATEMENT" is required.

FETAL CELL CULTURE

We will culture fetal cells from direct amniotic fluid, chorionic villi, or products of conception (POC) via Test Code #995 (cost \$250). Collect 10 ml -20 ml of direct amniotic fluid or 5 mg -10 mg cleaned CVS tissue (~15-20 cleaned villi) or 2mm x 2mm x 2mm fresh tissue (saline or culture media at room temperature). CPT code 88235 for amniotic fluid / chorionic villi or 88233 for POC specimens.

PRENATAL HEALTHCARE PROVIDER'S STATEMENT

This statement is required and applies to all cases of ongoing pregnancy.

MOTHER'S INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	MOTHER'S DATE OF BIRTH ____/____/____ <small>MONTH DAY YEAR</small>
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My signature below indicates all of the following:

- I take responsibility for the appropriateness of the requested testing.
- I have explained the purpose of the prenatal testing I have requested.
- I have provided appropriate genetic counseling to my patient.
- I have given the opportunity for the patient to ask questions.
- I am responsible for obtaining written or verbal informed consent (ensuring my patient understands risks, benefits and limitations of the testing and the implications of the results).

HEALTHCARE PROVIDER SIGNATURE

PRINTED NAME

DATE

FOR NY SPECIMENS ONLY: Retention of Unused DNA

PreventionGenetics' general policy is to retain all excess DNA from patient testing indefinitely. This allows for easier ordering of additional testing in the future and saves considerable phlebotomy and shipping costs to the patient and healthcare system. Excess DNA specimens can also be used for quality control measures. New York (NY) law requires patient consent in order to retain excess DNA beyond 60 days. If patient specimen was collected in NY and this statement is not signed, excess DNA will be discarded 30 days after testing is completed.

I have obtained consent from my patient(s) for PreventionGenetics to retain unused DNA from all specimens (i.e., fetal, maternal, paternal, proband, etc.) for potential future testing ordered by his/her healthcare provider and for quality control.

HEALTHCARE PROVIDER SIGNATURE ON BEHALF OF PATIENT

PRINTED NAME

DATE

PRENATAL TEST REQUISITION FORM

ORDERING CHECKLIST

- Fetal Specimen
- Family member specimen(s) - as needed
- Prenatal Healthcare Provider Statement included

INSTRUCTIONS

- All testing must be ordered by a qualified Healthcare Provider.
- Fetal, parental and/or proband information must be completed on one form
- See Prenatal Guidelines for further ordering details

PERSON COMPLETING FORM	CONTACT (PHONE OR EMAIL)	DATE OF REQUEST ____/____/____ <small>MONTH DAY YEAR</small>
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FETAL AND MATERNAL INFORMATION

LAST (FAMILY) NAME	MOTHER'S FIRST NAME (FETUS OF)	MI	MOTHER'S DATE OF BIRTH ____/____/____ <small>MONTH DAY YEAR</small>
MATERNAL ID CODE	FETAL SAMPLE DATE COLLECTED ____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM ____/____/____ <small>TIME MONTH DAY YEAR</small>		FETAL SEX <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown <input type="checkbox"/> Ambiguous Based On: _____
PRENATAL SPECIMEN SOURCE <input type="checkbox"/> Cell Culture, Source _____ <input type="checkbox"/> Extracted DNA, Source _____ <input type="checkbox"/> Direct Amniotic Fluid <input type="checkbox"/> Direct CVS <input type="checkbox"/> Fetal Blood (PUBS) <input type="checkbox"/> Other, Source _____			
WILL A BACKUP SAMPLE BE MAINTAINED AT ANOTHER LOCATION? <input type="checkbox"/> NO <input type="checkbox"/> YES			

ADDITIONAL MATERNAL INFORMATION

MATERNAL SPECIMEN SOURCE <input type="checkbox"/> Whole Blood 5mL EDTA - Preferred <input type="checkbox"/> Other, Source _____ <input type="checkbox"/> Extracted DNA, Source _____ <input type="checkbox"/> Saliva	DATE COLLECTED ____/____/____ <small>MONTH DAY YEAR</small>
CLINICAL FEATURES <input type="checkbox"/> Unaffected <input type="checkbox"/> Unknown <input type="checkbox"/> Affected, features _____	BLOOD TRANSFUSION <input type="checkbox"/> NO <input type="checkbox"/> Within Last 30 Days, Date ____/____/____ <small>MONTH DAY YEAR</small>
GEOANCESTRY / ETHNICITY	BONE MARROW TRANSPLANT <input type="checkbox"/> NO <input type="checkbox"/> YES ____/____/____ <small>MONTH DAY YEAR</small>
HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics? <input type="checkbox"/> NO <input type="checkbox"/> YES, PG ID# _____	

PREGNANCY HISTORY

GESTATIONAL AGE AT SAMPLE COLLECTION ____ <input type="checkbox"/> by U/S <input type="checkbox"/> by LMP	IS THIS AN ONGOING PREGNANCY? <input type="checkbox"/> No <input type="checkbox"/> Yes	DONOR PREGNANCY <input type="checkbox"/> No <input type="checkbox"/> Yes	MULTIPLE GESTATION PREGNANCY? <input type="checkbox"/> Twins <input type="checkbox"/> Triplets <input type="checkbox"/> Other _____
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PATERNAL INFORMATION (Targeted Prenatal Testing Only, if needed)

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH ____/____/____ <small>MONTH DAY YEAR</small>
PATERNAL SPECIMEN SOURCE <input type="checkbox"/> Whole Blood 5mL EDTA - Preferred <input type="checkbox"/> Other, Source _____ <input type="checkbox"/> Extracted DNA, Source _____ <input type="checkbox"/> Saliva		DATE COLLECTED ____/____/____ <small>MONTH DAY YEAR</small>	
CLINICAL FEATURES <input type="checkbox"/> Unaffected <input type="checkbox"/> Unknown <input type="checkbox"/> Affected, features _____		BLOOD TRANSFUSION <input type="checkbox"/> NO <input type="checkbox"/> Within Last 30 Days, Date ____/____/____ <small>MONTH DAY YEAR</small>	
GEOANCESTRY / ETHNICITY		BONE MARROW TRANSPLANT <input type="checkbox"/> NO <input type="checkbox"/> YES ____/____/____ <small>MONTH DAY YEAR</small>	
HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics? <input type="checkbox"/> NO <input type="checkbox"/> YES, PG ID# _____			

*OVER FOR ADDITIONAL FAMILY MEMBERS
AND ADDITIONAL HEALTH HISTORY*

PREVENTIONGENETICS USE ONLY

ADDITIONAL FAMILY MEMBER INFORMATION (Targeted Prenatal Testing Only, if needed)

LAST (FAMILY) NAME		FIRST NAME	MI	DATE OF BIRTH ____/____/____ <small>MONTH DAY YEAR</small>
SPECIMEN SOURCE <input type="checkbox"/> Whole Blood 5mL EDTA - Preferred <input type="checkbox"/> Extracted DNA, Source _____ <input type="checkbox"/> Saliva		DATE COLLECTED ____/____/____ <small>MONTH DAY YEAR</small>		PATIENT ID CODE
CLINICAL FEATURES <input type="checkbox"/> Unaffected <input type="checkbox"/> Unknown <input type="checkbox"/> Affected, features _____		GEOANCESTRY / ETHNICITY		BONE MARROW TRANSPLANT <input type="checkbox"/> NO <input type="checkbox"/> YES
HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics? <input type="checkbox"/> NO <input type="checkbox"/> YES, PG ID# _____		SEX <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown/Other		BLOOD TRANSFUSION <input type="checkbox"/> NO <input type="checkbox"/> Within Last 30 Days, Date ____/____/____ <small>MONTH DAY YEAR</small>

CLINICAL INFORMATION (REQUIRED)

CLINICAL INDICATION

CHOOSE ALL THAT APPLY

- | | |
|--|---|
| <input type="checkbox"/> Advanced maternal age | <input type="checkbox"/> Family history (specify relationship to patient, clinical and lab details) |
| <input type="checkbox"/> Abnormal cell-free fetal DNA test (specify below) | <input type="checkbox"/> Fetal loss / stillbirth / POC |
| <input type="checkbox"/> Abnormal maternal serum screen (specify below) | <input type="checkbox"/> Parental concern / anxiety |
| <input type="checkbox"/> Abnormal fetal ultrasound (specify below, attach report if available) | <input type="checkbox"/> Other, specify _____ |

FAMILY INFORMATION

SNP MICRO-ARRAY MAY DETECT IDENTITY BY DESCENT *Are parents known to be related? (Describe relationship)*

FAMILY MEMBER(S) PREVIOUSLY TESTED *Specify ID# and relationship.*

FAMILY MEMBER(S) WITH ABNORMAL GENETIC TESTING RESULTS *Specify results, relationship, and provide report, if possible.*

ADDITIONAL CLINICAL INFORMATION (STRONGLY RECOMMENDED)

Other relevant clinical information (labs, ultrasound results, biopsies, other genetic testing performed, etc. Please attach a pedigree, if available.

PREVENTIONGENETICS USE ONLY

TEST SELECTION

FETAL TEST SELECTION

List below the tests that are to be performed. If targeted testing, please include details. For other tests, the Test Numbers and Names can be obtained from our web site. Please include any special instructions in the comments section. The tests will be performed in the order listed unless otherwise specified. Unless requested, we will run Sanger panels sequentially as listed in our test descriptions.

We offer a STAT option for Sanger sequencing and gene-centric aCGH. The great majority of STAT tests are completed within 8 calendar days. If we are unable to complete STAT requests within 10 days, surcharge will be waived. NextGen panels are not available to be ordered STAT. All testing related to an ongoing pregnancy is courtesy expedited. We require at least one parental specimen be sent for prenatal testing. SEE PRENATAL GUIDELINES FOR MORE INFORMATION.

SELECT TEST OF INTEREST OR FILL IN DESIRED TEST CODE

TEST CODE	TEST NAME	GENE(S)	VARIANT(S)
<input type="checkbox"/> 990	Targeted Prenatal Testing for Known Familial Variants. Includes STAT turnaround time (8-10 calendar days); positive control required.		
<input type="checkbox"/> 3780	Prenatal Rapid CMA with Cell Culture	SPECIAL INSTRUCTIONS <input type="checkbox"/> CONCURRENT TESTING All tests ordered and genes to be run simultaneously. <input type="checkbox"/> STAT TESTING** For STAT add 25% to price. Tests ordered will be run concurrently unless otherwise instructed. <input type="checkbox"/> HOLD TESTING Pending MOH approval, insurance pre-authorization, etc. <input type="checkbox"/> SPECIMEN COLLECTED IN NEW YORK STATE Include New York State Non-Permitted Laboratory Test Request approval letter and Genetic Testing Healthcare Provider Statement if test is not NY state approved. For a list of tests that are NY state approved see website.	
<input type="checkbox"/> 995	Fetal Cell Culture Only		
<input type="checkbox"/>			
<input type="checkbox"/>			

MATERNAL TEST SELECTION

Targeted Prenatal Testing (Test Code 990), positive controls from parents and/or proband are required. Maternal Cell Contamination (MCC) Studies (Test Code 800, CPT Code 81265) are strongly recommended for any fetal testing and offered at no additional charge. If maternal sample being sent for full gene sequencing (Sanger or NGS), complete the fillable Test Code and Test Name section with test desired.

TEST	GENE(S)	VARIANT(S)	REPORT WANTED?
<input type="checkbox"/> Positive Control for Variant(s) Test Code 100, 200, or 300 - no charge			As part of Test Code 990, parental carrier results can be issued upon request at no additional charge <input type="checkbox"/> YES <input type="checkbox"/> NO IF BLANK, NO REPORT WILL BE ISSUED.
<input type="checkbox"/> Maternal Cell Contamination (MCC) Study Test Code 800 - no charge			
<input type="checkbox"/>			<input type="checkbox"/> STAT TESTING Add 25% to price.

PATERNAL TEST SELECTION

For Targeted Prenatal Testing (Test Code 990), positive controls from parents and/or proband are required. If paternal sample being sent for full gene sequencing (Sanger or NGS), please complete the fillable Test Code and Name section with test desired.

TEST	GENE(S)	VARIANT(S)	REPORT WANTED?
<input type="checkbox"/> Positive Control for Variant(s) Test Code 100, 200, or 300 - no charge			As part of Test Code 990, parental carrier results can be issued upon request at no additional charge <input type="checkbox"/> YES <input type="checkbox"/> NO IF BLANK, NO REPORT WILL BE ISSUED.
<input type="checkbox"/>			
<input type="checkbox"/>			<input type="checkbox"/> STAT TESTING Add 25% to price.

ADDITIONAL FAMILY MEMBER TEST SELECTION

For Targeted Prenatal Testing (Test Code 990), positive controls from parents and/or proband are required.

TEST	GENE(S)	VARIANT(S)	ADDITIONAL INFORMATION
<input type="checkbox"/> Positive Control for Variant(s) Test Code 100, 200, or 300 - no charge			

PREVENTIONGENETICS USE ONLY

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, indicate them below.*

PROVIDER INFORMATION

INSTITUTION

ADDRESS (City, State, Country and Postal Code)

REQUESTING PHYSICIAN (First, Last, Degree)

REQUESTING GENETIC COUNSELOR OR ALLIED PROVIDER (First, Last, Degree)

PHONE NUMBER

NPI#

PHONE NUMBER

NPI#

EMAIL

EMAIL

TEST REPORTING INSTRUCTIONS

Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP Use above email address

DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.

DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____ - _____

TEST REPORTING INSTRUCTIONS

Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP Use above email address

DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.

DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____ - _____

SENDOUT LABORATORY COMPLETE ONLY IF REPORT IS NEEDED

OTHER

INSTITUTION / CONTACT

INSTITUTION / CONTACT

ADDRESS (City, State, Country and Postal Code)

ADDRESS (City, State, Country and Postal Code)

PHONE NUMBER

NPI# (Where Applicable)

PHONE NUMBER

NPI# (Where Applicable)

EMAIL

EMAIL

TEST REPORTING INSTRUCTIONS

Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP Use above email address

DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.

DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____ - _____

TEST REPORTING INSTRUCTIONS

Our preferred method of report transmission is email via ZixCorp

SECURE EMAIL VIA ZIXCORP Use above email address

DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE.

DO NOT EMAIL RESULTS. Send via fax (provide fax number):

(_____) _____ - _____

As the ordering Healthcare Provider, I confirm I have obtained the patient's informed consent, either verbally or in writing, to perform this test. I further confirm the patient has been appropriately counseled and understands the risks, benefits, and limitations of this genetic testing and the implications of the results.

PREVENTIONGENETICS USE ONLY

BILLING - PLEASE SELECT INSTITUTIONAL OR SELF-PAY WITH OPTION TO SUBMIT TO INSURANCE

PATIENT TESTING WILL BE DELAYED UNTIL ALL OF THE BILLING REQUIREMENTS HAVE BEEN MET. PLEASE PRINT CLEARLY.

If the patient's specimen is collected in New York, a New York State Non-Permitted Laboratory Test Request approval letter (where applicable) and Genetic Testing Healthcare Provider Statement (see website) must be included before testing will proceed.

INSTITUTIONAL BILLING		BILLING INSTITUTION		PO NUMBER	
CONTACT		PHONE NUMBER		EMAIL	
ADDRESS		CITY		STATE	ZIP
BILLING ACCOUNT NUMBER <input type="checkbox"/> UPDATED INFO		COPY OF TEST REPORT(S) FOR BILLING			
EMAIL INVOICE VIA ZIXCORP (PROVIDE EMAIL ADDRESS)		<input type="checkbox"/> EMAIL (VIA ZIXCORP) _____ <input type="checkbox"/> OTHER (PLEASE SPECIFY) _____			

SELF-PAY						**THIS SECTION MUST BE FILLED OUT COMPLETELY**					
RESPONSIBLE PARTY'S NAME (MUST BE 18 YEARS OR OLDER)				PHONE NUMBER		EMAIL					
ADDRESS				CITY		STATE	ZIP				
ACCEPTANCE of financial responsibility for genetic testing PREVENTIONGENETICS CANNOT PROCEED WITH TESTING OF THE SPECIMEN WITHOUT A SIGNATURE BELOW. My signature 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 NUMBER (VISA, DISCOVER, OR MASTERCARD ONLY)				EXPIRATION DATE		3-DIGIT SECURITY CODE			
My signature authorizes PreventionGenetics to charge my credit card for services for which I am responsible.											
SIGNATURE _____				DATE _____							
<input type="checkbox"/> SUBMIT CLAIM TO INSURANCE (OPTIONAL)											
POLICYHOLDER'S NAME (REQUIRED)				PLEASE INDICATE THE TYPE OF INSURANCE <input type="checkbox"/> PRIVATE <input type="checkbox"/> MEDICARE <input type="checkbox"/> WI MEDICAID <i>We only accept WI Medicaid</i>							
PRIMARY INSURANCE COMPANY NAME (REQUIRED)						<input type="checkbox"/> ATTACH A COPY OF INSURANCE CARD both sides					
INSURANCE COMPANY ADDRESS - CLAIMS				CITY		STATE	ZIP				
ICD-10 CODES (REQUIRED)		POLICY ID#		GROUP #		AUTHORIZATION #					
PLEASE ATTACH THE FOLLOWING DOCUMENTATION <i>PreventionGenetics cannot proceed with testing of the specimen until all information is received.</i>											
<input type="checkbox"/> NPI # of Requesting Physician _____				<input type="checkbox"/> Relevant Medical Records addressing medical necessity and/or Letter of Medical Necessity				<input type="checkbox"/> SHARE RESULTS of benefits investigation with patient directly via email provided above			
<input type="checkbox"/> MEDICARE – signed ABN Form completed IN FULL								or FAX # (_____) _____ - _____			
<input type="checkbox"/> AUTHORIZATION NUMBER or letter of agreement from Insurance Company (if available). If not included, we will routinely perform pre-verification prior to initiating testing and will relay information to ordering provider.											
AUTHORIZATION to assign benefits and accept financial responsibility for my account 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. My signature indicates that I accept financial responsibility for all fees associated with this genetic testing order.											
<input type="checkbox"/> Proceed with testing once all required information has been sent, regardless of benefit investigation (to avoid testing being placed ON HOLD pending pre-authorization, if needed). Option does NOT apply for Medicaid.											
SIGNATURE OF RESPONSIBLE PARTY _____				PRINTED NAME OF RESPONSIBLE PARTY _____				DATE _____			

PREFERRED SPECIMEN REQUIREMENTS

PLEASE CONTACT US WITH ADDITIONAL SPECIMEN REQUIREMENT QUESTIONS.

WHOLE BLOOD

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

DNA

Send in screw cap tube at least 5 µg -10 µg of purified DNA at a concentration of at least 20 ng/µL for NGS and Sanger tests and at least 5 µg of purified DNA at a concentration of at least 100 ng/µL for gene-centric aCGH, MLPA, and CMA tests, minimum 2 µg for limited specimens. Indicate concentration on tube label. For requests requiring more than one test, send an additional 5 µg DNA per test ordered when possible.

SALIVA

Oragene™ or GeneFIX™ Saliva Collection kit used according to manufacturer instructions.

FETAL (CVS / AMNIOCYTES) AND OTHER CELL CULTURES

Culture and send at least two, T25 flasks of confluent cells. For sequencing or gene-centric aCGH panels, two flasks are often sufficient; however, some panels may require additional flasks (dependent on size of genes, amount of Sanger sequencing required, etc.). Multiple test requests may also require additional flasks. Please contact us for details. We strongly recommend maintaining a back-up culture. Fetal cell cultures are available at PreventionGenetics from direct amniotic fluid, chorionic villi, products of conception (POC), or other tissue via Test Code #995 (cost \$250). Collect 10 ml - 20 ml of direct amniotic fluid or 5 mg - 10 mg cleaned CVS tissue (~15-20 cleaned villi) or 2mm x 2mm x 2mm fresh tissue. CPT code 88235 for amniotic fluid/chorionic villi or 88233 for POC or tissue specimens.

	TEST METHOD	WHOLE BLOOD	DNA	SALIVA	CELL CULTURES	FRESH, FROZEN TISSUE	OCD-100 BUCCAL SWAB	DIRECT AMNIOTIC FLUID/CVS	OTHER
SEQUENCING	NextGen (NGS)	★	★	★	★	★	■	■ ^C	-
	PGxome® / PGxome Custom Panels	★	★ ^B	★	★ ^B	★	■	-	-
	Sanger	★	★	★	★	★	■	■ ^C	Semen ^D
DEL / DUP	Gene-centric aCGH	★	★	■	■	★	-	■ ^C	-
	MLPA	★	★ ^A	ONLY TEST #1941	★ ^A	-	■	-	-
	Chromosomal Microarray (CMA)	★	★	■	★	★	-	■	-

EXCEPTIONS

- A - Cell cultures and DNA extracted from CVS and amniocytes not accepted for MLPA; DNA extracted from saliva (except test #1941) also not accepted.
- B - Cell cultures and DNA extracted from CVS and amniocytes acceptable for PGxome for non-ongoing pregnancies only.
- C - Direct prenatal specimen types most appropriate for targeted prenatal familial variant testing (Test Code #990), and strongly discouraged for full gene and panel tests. Back-up culture highly recommended.
- D - Semen: Collect 1-2 vials and flash freeze. Vials to be sent frozen (preferably on dry ice). Contact us for details.

KEY

- ★ PREFERRED
- ACCEPTED
- NOT ACCEPTED

FRESH, FROZEN TISSUE

Collect 2mm x 2mm x 2mm tissue and flash freeze. Tissue to be sent frozen (preferably dry ice). If cell culture is desired, tissue should not be frozen. Contact us for additional details.

OCD-100 BUCCAL SWAB

OCD-100 Buccal Swab used according to manufacturer instructions. Buccal swabs are most appropriate for targeted, known variant testing.

DIRECT AMNIOTIC FLUID / CHORIONIC VILLI

Collect 10 ml -20 ml of direct amniotic fluid or 5 mg -10 mg cleaned CVS tissue (~15-20 cleaned villi). We strongly recommend maintaining a local back-up culture. Fetal cell cultures available (Test Code #995, \$250).

SHIPPING AND HANDLING INSTRUCTIONS

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. Specimen deliveries are accepted 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, contact us to make arrangements. Saturday delivery should be avoided when possible as prenatal specimens are not processed over the weekend. Holiday schedules will be posted on our website 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, AND POC

Send specimens overnight in an insulated, shatterproof container. Direct AF/CVS, POC, or tissue specimens can be sent in saline or culture media at room temperature for culturing at PreventionGenetics (Test Code #995, \$250).

PRENATAL TESTING

Please sign Prenatal Healthcare Provider's Statement for ongoing pregnancies and contact us in advance regarding prenatal test requests. When possible, ship prenatal samples to arrive at PreventionGenetics no later than Thursday.

DNA GENOTYPING PANEL

For quality control purposes, the Prevention Genetics 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 at PreventionGenetics. Visit our website at www.PGDNABank.com for more information. For questions about PGDNABanking, contact us at (715) 387-0484, ext. 151, or email: dnabanking@preventiongenetics.com.

CONTACT US

For additional questions or concerns, contact a Client Service Representatives at (715) 387-0484, ext. 0, or our Genetic Counseling Team at option 2, or email: clinicaldnatesting@preventiongenetics.com.

MAILING ADDRESS

PreventionGenetics - Diagnostic Lab
3800 S. Business Park Avenue
Marshfield, Wisconsin 54449 USA

TESTING KITS

Clinical testing kits with prepaid return shipping are available for U.S. Clients. Clinical testing kits are provided to International clients without the return postage. Submit requests through our website or contact a Client Service Representatives at (715) 387-0484, ext. 0.