PREVENTION GENETICS

DISEASE PREVENTION THROUGH GENETIC TESTING

PREVENTIONGENETICS USE ONLY

Test information is available on our website:
www.PreventionGenetics.com

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

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 does not perform cell culture.

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

At this time, PreventionGenetics is not validated to offer prenatal testing for MLPA or repeat expansion testing. We cannot 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.

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.

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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
			_____ / _____ / _____ MONTH DAY YEAR

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 for PreventionGenetics to retain unused DNA for potential future testing ordered by her healthcare provider and for quality control testing.

HEALTHCARE PROVIDER SIGNATURE ON BEHALF OF PATIENT _____ PRINTED NAME _____ DATE _____

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All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

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
		____ / ____ / ____ MONTH / DAY / YEAR

FETAL AND MAternal INFORMATION

LAST (FAMILY) NAME	MOTHER'S FIRST NAME (FETUS OF)	MI	MOTHER'S DATE OF BIRTH
			____ / ____ / ____ MONTH / DAY / YEAR

MATERNAL ID CODE	FETAL SAMPLE DATE COLLECTED	ONGOING PREGNANCY
	MONTH ____ / DAY ____ / YEAR ____	☐ NO ☐ YES EDC: ____

SPECIMEN SOURCE

☐ Cell Culture, Source ____
☐ Direct Amniotic Fluid
☐ Other ____
☐ Extracted DNA, Source ____
☐ Direct CVS

FETAL SEX

☐ Male ☐ Female
☐ Unknown based on: ____

ADDITIONAL MATERNAL INFORMATION

SPECIMEN SOURCE

☐ Whole Blood
☐ Extracted DNA, Source ____
☐ Tissue, Source ____
☐ Cell Culture, Source ____
☐ Other ____

DATE COLLECTED

MONTH ____ / DAY ____ / YEAR ____

CLINICAL FEATURES

☐ Unaffected ☐ Unknown ☐ Affected, features ____

GEOANCESTRY / ETHNICITY

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, PG ID# ____

BLOOD TRANSFUSION

☐ NO
☐ Within Last 30 Days, Date
____ / ____ / ____ MONTH / DAY / YEAR

BONE MARROW TRANSPLANT

☐ NO
☐ YES
____ / ____ / ____ MONTH / DAY / YEAR

PATERNAL INFORMATION (Targeted Prenatal Testing Only, if needed)

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH
			____ / ____ / ____ MONTH / DAY / YEAR

SPECIMEN SOURCE

☐ Whole Blood
☐ Extracted DNA, Source ____
☐ Tissue, Source ____
☐ Cell Culture, Source ____
☐ Other ____

DATE COLLECTED

____ / ____ / ____ MONTH / DAY / YEAR

PATIENT ID CODE

CLINICAL FEATURES

☐ Unaffected ☐ Unknown ☐ Affected, features ____

GEOANCESTRY / ETHNICITY

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, PG ID# ____

BLOOD TRANSFUSION

☐ NO
☐ Within Last 30 Days, Date
____ / ____ / ____ MONTH / DAY / YEAR

BONE MARROW TRANSPLANT

☐ NO
☐ YES
____ / ____ / ____ MONTH / DAY / YEAR

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

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH
			____ / ____ / ____ MONTH / DAY / YEAR

SPECIMEN SOURCE

☐ Whole Blood
☐ Extracted DNA, Source ____
☐ Tissue, Source ____
☐ Cell Culture, Source ____
☐ Other ____

DATE COLLECTED

____ / ____ / ____ MONTH / DAY / YEAR

PATIENT ID CODE

CLINICAL FEATURES

☐ Unaffected ☐ Unknown ☐ Affected, features ____

GEOANCESTRY / ETHNICITY

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, PG ID# ____

SEX

☐ Male ☐ Female ☐ Unknown/Other

BLOOD TRANSFUSION

☐ NO
☐ Within Last 30 Days, Date
____ / ____ / ____ MONTH / DAY / YEAR

BONE MARROW TRANSPLANT

☐ NO
☐ YES
____ / ____ / ____ MONTH / DAY / YEAR

PREVENTION GENETICS

DISEASE PREVENTION THROUGH GENETIC TESTING

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THIS FORM MUST ACCOMPANY ALL SPECIMENS

PRENATAL RAPID CMA
TEST REQUISITION FORM

CLINICAL INDICATION *CHOOSE ALL THAT APPLY*

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

Specify details here: _____

PREGNANCY HISTORY

GESTATIONAL AGE AT SAMPLE COLLECTION	FETAL SEX	IS THIS AN ONGOING PREGNANCY?	DONOR PREGNANCY	MULTIPLE GESTATION PREGNANCY?
_____ ☐ by U/S ☐ by LMP	☐ Male ☐ Female ☐ Unknown ☐ Ambiguous	☐ No ☐ Yes	☐ No ☐ Yes	☐ Twins ☐ Triplets ☐ Other _____

PRIOR KARYOTYPE OR OTHER GENETIC TESTING *Provide results and copy of report*

SPECIMEN INFORMATION

DATE COLLECTED

_____ / _____ / _____
MONTH *DAY* *YEAR*

TIME _____ ☐ am ☐ pm

PRENATAL SPECIMENS *Rapid CMA is only available on amniotic fluid and DNA*

- ☐ Amniotic fluid, choose one: ☐ Direct ☐ Cultured
- ☐ Extracted DNA, source _____
- ☐ Fetal Blood (PUBS)
- ☐ Other, Source _____

PARENTAL SPECIMENS

- ☐ Saliva
- ☐ Peripheral Blood (5 mL EDTA) ***PREFERRED PARENTAL SAMPLE***
- ☐ Other, Source _____

IF SENDING FATHER'S SAMPLE
If billing differ, please submit separate requisition

Father's Name_____ DOB_____

WILL A BACKUP SAMPLE BE MAINTAINED AT ANOTHER LOCATION?

☐ NO ☐ YES

FAMILY INFORMATION

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

FAMILY MEMBER PREVIOUSLY TESTED *Specify ID# and relationship*

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

TEST SELECTION

	TEST CODE	TEST NAME
☐	3780	**Rapid Prenatal Chromosomal Microarray** Price: $1390 Turn Around Time: 3-6 days MCC (Test 800) included and required

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DISEASE PREVENTION THROUGH GENETIC TESTING

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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.

	TEST CODE	TEST NAME	GENE(S)	VARIANT(S)
☐	990	**Targeted Prenatal Testing for Known Familial Variants.** Includes STAT turnaround time (8-10 calendar days); positive control required.		
☐	TEST CODE	TEST NAME		
☐	TEST CODE	TEST NAME		
☐	TEST CODE	TEST NAME		

COMMENTS:

SPECIAL INSTRUCTIONS

☐ **CONCURRENT TESTING**
All tests ordered and genes to be run simultaneously.

☐ **STAT TESTING****
For STAT add 25% to price. Tests ordered will be run concurrently unless otherwise instructed.

☐ **HOLD TESTING**
Pending MOH approval, insurance pre-authorization, etc.

☐ **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.

CLINICAL INFORMATION *(STRONGLY RECOMMENDED)*

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

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?
☐	**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 ☐ YES ☐ NO IF BLANK, NO REPORT WILL BE ISSUED.
☐	**Maternal Cell Contamination (MCC) Study** Test Code 800 - no charge			

	TEST CODE	TEST NAME	
☐			☐ **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?
☐	**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 ☐ YES ☐ NO IF BLANK, NO REPORT WILL BE ISSUED.

	TEST CODE	TEST NAME	
☐			☐ **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
☐	**Positive Control for Variant(s)** Test Code 100, 200, or 300 - no charge			

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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, 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

INSTITUTION / CONTACT

ADDRESS (City, State, Country and Postal Code)

PHONE NUMBER	**NPI# (Where Applicable)**
EMAIL	

TEST REPORTING INSTRUCTIONS
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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):
(_____) _____-_____

OTHER

INSTITUTION / CONTACT

ADDRESS (City, State, Country and Postal Code)

PHONE NUMBER	**NPI# (Where Applicable)**
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):
(_____) _____-_____

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.

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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.

1 ☐ INSTITUTIONAL BILLING

BILLING INSTITUTION		PO NUMBER	
CONTACT	PHONE NUMBER	EMAIL	
ADDRESS	CITY	STATE	ZIP
BILLING ACCOUNT NUMBER ☐ UPDATED INFO		COPY OF TEST REPORT(S) FOR BILLING	
EMAIL INVOICE VIA ZIXCORP (PROVIDE EMAIL ADDRESS)		☐ EMAIL (VIA ZIXCORP) _____	
		☐ OTHER (PLEASE SPECIFY) _____	

2a ☐ SELF-PAY

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 _____

2b ☐ SUBMIT CLAIM TO INSURANCE *MUST ALSO COMPLETE SECTION 2a*

POLICYHOLDER'S NAME (REQUIRED)		PLEASE INDICATE THE TYPE OF INSURANCE ☐ PRIVATE ☐ MEDICARE ☐ WI MEDICAID *We only accept WI Medicaid*	
PRIMARY INSURANCE COMPANY NAME (REQUIRED)		☐ *ATTACH 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 *PreventionGenetics cannot proceed with testing of the specimen until all information is received.*

☐ NPI # of Requesting Physician _____

☐ *MEDICARE – signed ABN Form completed IN FULL*

☐ *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.

☐ *Relevant Medical Records addressing medical necessity and/or Letter of Medical Necessity*

☐ *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

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.

☐ 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 _____

SPECIMEN REQUIREMENTS AND TURNAROUND TIMES (TAT)

PREVENTIONGENETICS PREFERRED SPECIMEN TYPES

PLEASE CONTACT US WITH ADDITIONAL SPECIMEN REQUIREMENT QUESTIONS.

STAT TAT (8-10 calendar days) available at a 25% surcharge for Sanger Sequencing and aCGH. Cannot be guaranteed for aCGH.

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™ 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. Contact us for details. We strongly recommend maintaining a local back-up culture; PreventionGenetics does not culture cells.

	TEST METHOD	WHOLE BLOOD	DNA	SALIVA	CELL CULTURES	FRESH, FROZEN TISSUE	BUCCAL SWABS	DIRECT AMNIOTIC FLUID/CVS	OTHER	TURN AROUND TIME (TAT)
SEQUENCING	NextGen (NGS)	★	★	★	★	★	■	■ C	–	28 days
	PGxome™/ PGxome Custom Panels	★	★ B	★	★ B	★	–	–	–	6 weeks
	Sanger	★	★	★	★	★	■	■ C	Semen D	18 days
DEL / DUP	Gene-centric aCGH	★	★	■	■	★	–	■ C	–	28 days
	MLPA	★	★ A	ONLY TEST #1941	★ A	–	–	–	–	20 days
	Chromosomal Microarray (CMA)	★	★	■	★	★	–	■	–	20 days

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). Contact us for additional details.

BUCCAL SWABS

Buccal swabs are most appropriate for targeted, known variant testing. Collect 3-6 buccal swabs for targeted, known variant testing and 10-20 buccal swabs for sequencing of full gene(s).

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.

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 AND DIRECT AF/CVS

We are NOT able to culture cells. Send specimens overnight in an insulated, shatterproof container.

ADDRESS

Diagnostic Lab
PreventionGenetics
3800 S. Business Park Ave.
Marshfield, WI 54449
USA

TESTING KITS

Clinical testing kits with prepaid return shipping are available for U.S. Clients. We are able to provide clinical testing kits to International clients without the return postage. To order test kits, submit requests through our electronic order form (see website) or contact our Client Service Representatives at (715) 387-0484, ext. 0.

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. PreventionGenetics does not culture cells.

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 at PreventionGenetics. Visit our website at www.PGDNABank.com for information about the process and forms. For questions related to PGDNABanking, 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 option 2, or email: clinicaldnatesting@preventiongenetics.com.