PREVENTION GENETICS

DISEASE PREVENTION THROUGH GENETIC TESTING

# Prenatal Test Requisition Form and Testing Guidelines

March 14, 2016

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 accept fetal DNA, fetal tissue, cultured fetal cells, or direct CVS/amniotic fluid. However, acceptable specimen type is dependent on the fetal testing requested. 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 contamination 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 mutation, blood or DNA from the mother is strongly encouraged to be sent for the contamination test. We do not charge extra for Maternal Cell Contamination studies, but the CPT Code, 81265, will be included on invoices and insurance claims as appropriate.

At this time, PreventionGenetics does not offer aCGH for prenatal specimens, however, if a copy number variation (CNV) was able to be confirmed by an alternate method (PCR) in a proband tested at PreventionGenetics, we may be able to offer targeted deletion or duplication testing prenatally. Please call and speak to one our genetic counselors to see if this is a possibility. For any CNV where the mother is a carrier, we are unable to offer targeted testing for that CNV.

PreventionGenetics does not perform prenatal testing for gender. We will also not report fetal gender unless this is critical for interpretation of test results. PreventionGenetics does not perform pre-implantation DNA testing.

See our "Specimen Requirements" for acceptable prenatal specimens (page 7 of Prenatal Test Requisition Form).

**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. There is no additional charge for parental testing or for maternal cell contamination testing, however, additional CPT codes for parental and MCC testing may be included at time of invoicing.
Turnaround Time: 10 calendar days from receipt of specimen *and* signed PROVIDER'S STATEMENT.

**Next-Gen Sequencing for Ongoing Pregnancy (see standard prices listed on our web site)**
We will also perform Next-Gen tests for ongoing pregnancies. We expect that the ordering provider will take responsibility for the appropriateness of the requested testing. There is no additional charge for maternal cell contamination testing.
Turnaround Time: A maximum of 45 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 and anticipate results in 3-4 weeks.

**Full Gene Sanger Sequencing for Ongoing Pregnancy (see standard prices listed on our web site)**
We will also perform Sanger full gene sequencing tests for ongoing pregnancies. We expect that the ordering provider will take responsibility for the appropriateness of the requested testing. There is no additional charge for maternal cell contamination testing.
Turnaround Time: Nearly all results are available within 20 days from date of specimen and signed PROVIDER'S STATEMENT receipt for a single gene. Our STAT option with a 10 day turnaround time may also be selected for an *additional* 25% charge. For multiple gene tests under the STAT option, the tests will be performed simultaneously rather than sequentially.

**Testing in Cases of Fetal Demise or Pregnancy Termination (see standard prices listed on our web site)**
In the case of fetal demise or pregnancy termination, no "PRENATAL HEALTH CARE PROVIDER'S STATEMENT" is required. Our standard specimen requirements and turnaround times apply.

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Office use only

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

# PRENATAL HEALTH CARE PROVIDER'S STATEMENT*

September 12, 2012

***Note**: **This Statement is required, and applies to all cases of ongoing pregnancy.**

**Mother's Name: _____**

**Date of Birth: _____**

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 that 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 that my patient understands risks, benefits and limitations of the testing and the implications of the results).

_____ _____
**Health Care Provider Signature** **Date**

_____
**Printed Name**

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# Prenatal Test Requisition Form

(revised 3/14/2016)

| Person completing form | Contact Information (phone or email) | Date of Request |
|---|---|---|
| | | |

**Ordering Checklist:**

- ☐ Fetal specimen
- ☐ Family member specimen(s) – as needed
- ☐ Prenatal Healthcare Provider Statement (enclosed)

**Instructions:**

- All testing must be ordered by a qualified healthcare provider.
- Fetal, parental and/or proband information to be completed on one form.
- Please see Prenatal Guidelines above for further details.

## 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: Month Day Year | | Ongoing pregnancy? ☐ Yes ☐ No EDC: |
| Fetal Specimen Source: ☐ Cell Culture Source: ☐ Extracted DNA Source: ☐ Direct Amniotic Fluid ☐ Direct CVS ☐ Other: | | | Fetal Gender: ☐ Male ☐ Female ☐ Unknown Based on: |

## Additional Maternal Information

| Maternal Specimen Source: ☐ Whole blood ☐ Extracted DNA Source: ☐ Cultured cells Source: ☐ Tissue Source: ☐ Other: | | | Date Collected: Month Day Year |
|---|---|---|---|
| Clinical Features: ☐ Unaffected ☐ Unknown ☐ Affected Features: | Bone marrow transplant or blood transfusion? ☐ Yes ☐ No If yes, circle which and provide date: | GeoAncestry/ Ethnicity | Has patient been tested previously at PreventionGenetics? ☐ Yes ☐ No If yes, PG ID#: |

## Paternal Information (Targeted Prenatal Testing Only, if needed)

| Last (Family) Name | First Name | MI | Date of Birth: Month Day Year | Patient ID Code |
|---|---|---|---|---|
| Paternal Specimen Source: ☐ Whole blood ☐ Extracted DNA Source: ☐ Cultured cells Source: ☐ Tissue Source: ☐ Other: | | | Date Collected: Month Day Year | |
| Clinical Features: ☐ Unaffected ☐ Unknown ☐ Affected Features: | Bone marrow transplant or blood transfusion? ☐ Yes ☐ No If yes, circle which and provide date: | GeoAncestry/ Ethnicity | Has patient been tested previously at PreventionGenetics? ☐ Yes ☐ No If yes, PG ID#: | |

## Additional Family Member Information (Targeted Prenatal Testing Only, if needed)

| Last (Family) Name | First Name | MI | Date of Birth: Month Day Year | Patient ID Code |
|---|---|---|---|---|
| Specimen Source: ☐ Whole blood ☐ Extracted DNA Source: ☐ Cultured cells Source: ☐ Tissue Source: ☐ Other: | | | Date Collected: Month Day Year | |
| Clinical Features: ☐ Unaffected ☐ Unknown ☐ Affected Features: | Bone marrow transplant or blood transfusion? ☐ Yes ☐ No If yes, circle which and provide date: | Gender: ☐ Male ☐ Female ☐ Unknown/Other | Has patient been tested previously at PreventionGenetics? ☐ Yes ☐ No If yes, PG ID#: | |

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# Test Selection

## Fetal Test Selection

*Please list below the tests that are to be performed. If targeted testing, please include those details. For other tests, the Test Numbers and Names can be obtained from our web site. Please include any special test instructions in the comments section. The tests will be performed in the order listed unless otherwise specified. Unless specifically requested, we will run Sanger panels sequentially as listed in our test descriptions. ** We offer a STAT option on our tests with ≤ 10 calendar day turnaround for Sanger sequencing tests. NextGen panels are not currently available to be ordered STAT. All testing related to an ongoing pregnancy is courtesy expedited. Gene-centric aCGH and CMA (Test Codes 600 & 2000) are not validated for prenatal sample types.*

| | | | |
|---|---|---|---|
| ☐ | ***Targeted Prenatal Testing for known familial variants (Test Code 990)*** *– includes STAT turnaround time (≤ 10 calendar day); positive control(s) required.* | **Gene(s):** | **Variant(s):** |

| | | |
|---|---|---|
| ☐ ***Test Code*** | ***Test Name*** | **Special Instructions**<br>☐ ***Concurrent Testing***<br>☐ ***STAT Testing*****<br>***(For STAT add 25% to price. Tests ordered will be run concurrently unless otherwise instructed.)***<br>☐ ***HOLD Testing*** ***(pending MOH approval, insurance preauth, etc.)*** |
| ☐ ***Test Code*** | ***Test Name*** | |
| ☐ ***Test Code*** | ***Test Name*** | |
| ***Comments:*** | | |

### Clinical Information *(Strongly Recommended)*

*Other relevant clinical information (Labs, ultrasound results, biopsies, other genetic testing performed, etc). Please attach pedigree if possible.*

## Maternal Test Selection

*For 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), please complete the fillable Test Code and Name section with test desired.*

| | | | |
|---|---|---|---|
| ☐ ***Positive control for variant(s) (Test Code 100, 200, or 300) – no charge***<br>☐ ***Maternal Cell Contamination (MCC) Studies (Test Code 800) – no charge*** | ***Gene(s):*** | ***Variant(s):*** | ***Report wanted?***<br>***As part of Test Code 990, parental carrier results can be issued upon request at no additional charge.*<br>☐ **Yes** ☐ **No** *If blank, parental report will not be issued.* |
| ☐ ***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.*

| | | | |
|---|---|---|---|
| ☐ ***Positive control for variant(s) (Test Code 100, 200, or 300) – no charge*** | ***Gene(s):*** | ***Variant(s):*** | ***Report wanted?*** ***As part of Test Code 990, parental carrier results can be issued upon request at no additional charge.*<br>☐ **Yes** ☐ **No** *If blank, parental report will not 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.*

| | | |
|---|---|---|
| ☐ ***Positive control for variant(s) (Test Code 100, 200, or 300)*** | ***Gene(s):*** | ***Variant(s):*** |

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# Provider/Laboratory Contact Information

- **Our preferred method of report transmission is email (via ShareFile). 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 ShareFile)* | | **Test Reporting Instructions** *Our preferred method of report transmission is email (via ShareFile)* | |
| ***Email (via ShareFile):*** ☐ *use above* | | ***Email (via ShareFile):*** ☐ *use above* | |
| ☐ ***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 ShareFile)* | **Test Reporting Instructions** *Our preferred method of report transmission is email (via ShareFile)* |
| ***Email (via ShareFile):*** ☐ *use above* | ***Email (via ShareFile):*** ☐ *use above* |
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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 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***<br>**Email Address:** | ***Copy of Test Report(s) for Billing***<br>☐ **Email (via ShareFile):** ☐ same as previous<br>☐ **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)* | *Primary Insurance Company Name (Required)* |
|---|---|---|
| | *Private / Medicare / WI Medicaid* | |

*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)***

### 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.

☐ Proceed with testing *once all required information has been sent*, regardless of preverification/preauthorization (to avoid testing being placed ON HOLD pending preauthorization, if needed). Option does NOT apply for Medicaid.

_____ _____ _____

***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 (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 not acceptable for gene-centric aCGH tests at this time.

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 CMA tests 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** (Maximum TAT: 45 days; Typical TAT: 3-4 weeks)

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** (Most all results reported within 20 days; Typical TAT: 1-2 weeks. Multiple genes are run sequentially unless concurrent testing is marked; TAT 20 days for first gene plus 10 days for each additional gene tested.)*

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** (Maximum TAT: 30 days; Typical TAT: 3-4 weeks)*

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 at this time.

**Whole-Genome Chromosomal Microarray** (Maximum TAT: 21 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 not accepted for CMA at this time.

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# Shipping Instructions & Additional Information

## Shipping/Handling Instructions

Please label all specimen containers with the patient 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 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.

| Address | Testing Kits |
|---|---|
| Diagnostic Lab<br>PreventionGenetics<br>3800 S. Business Park Ave.<br>Marshfield, WI 54449<br>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 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.