PREVENTION GENETICS

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 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.

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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(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 _____