

Prenatal Test Requisition Form and Testing Guidelines

August 10, 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 of 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: 8-10 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: 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 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: 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 8 calendar days. If we are unable to complete STAT requests within 10 days, the surcharge will be waived.

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.

Office
use
only

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