

Informed Consent for Chorionic Villi Sampling

By signing below, I, _____, request that Chorionic Villus Sampling (CVS) be performed by Dr. _____ for the purpose of prenatal diagnosis of certain birth defects. It has been explained to me by my doctor or by someone my doctor has designated and I understand that:

1. CVS is the withdrawal of a small sample of the placental tissue (chorionic villi) surrounding the fetus. CVS is performed transabdominally (with a needle inserted through the woman's abdominal wall). Ultrasound is used to guide the needle to the appropriate location in the placenta and protect the fetus.

2. CVS involves a small risk to both the mother and the fetus. The most common serious complication is miscarriage. In general, the risk for a miscarriage from CVS is less than 1 in 500. Minor complications include cramping, vaginal spotting, or slight leakage of amniotic fluid. Limb defects have been reported in the past in patients having CVS prior to 9.5 weeks and mostly when the CVS was done through the vagina/cervix. No such defects have ever been reported in cases done abdominally and after 9 weeks but cannot be excluded with 100% certainty.

3. Any particular attempt to obtain chorionic villi may be unsuccessful. Occasionally, even if sufficient tissue is obtained, laboratory analysis may not be possible or may not yield results. In these cases repeat CVS or amniocentesis may be offered.

4. The standard laboratory testing performed on a sample of chorionic villi can usually detect a high percentage of all chromosome disorders. There is approximately a 1 in 100 chance that the CVS results will be uncertain due to placental problems (focal placental mosaicism). In these cases the sample may show a mixture of normal and abnormal cells, and amniocentesis may be suggested. Also, there is an estimated 1 in 100 chance that CVS results will be normal when in fact the fetus has a chromosome abnormality.

5. Testing for other birth defects will not be performed unless indicated below.

6. Chorionic villi cannot be tested for neural tube defects. Therefore, it is usually recommended that a woman having CVS also have the blood test which can screen for open neural tube defects. This blood test, called the maternal serum alpha-fetoprotein (MSAFP) test, can be done at 16 to 18 weeks of pregnancy.

7. **Normal test results do not guarantee the birth of a normal child.** As in any laboratory test, there is a small possibility of error, and maternal cells may contaminate the sample. In addition, approximately 2-4% of all pregnancies have birth defects, which cannot be detected by testing the chorionic villi. Fetuses with normal chromosomes may still have anatomical defects as well as mental retardation.

8. Any part of this chorionic villi sample not used for diagnostic testing may be stored and used for medical research or education as long as my name and any other identifying information have been removed. All my questions were answered to my full satisfaction and I am fully aware of the risks and benefits of Chorionic villus sampling (CVS).

The reason for my having CVS is

My risk for abnormal results is

Signature of patient

Date

Witness

Date