



The new HARMONY prenatal test, developed by Ariosa Diagnostics and offered by Integrated Genetics, is a blood test that measures fetal DNA in a pregnant woman's blood.

What conditions are screened for in this test?

- ▶ Down syndrome (trisomy 21), trisomy 18, and trisomy 13. There is an option to screen for sex chromosome abnormalities such as Turner syndrome and Klinefelter syndrome and to learn the fetal gender. Gender can be determined with >99% accuracy in 95% of samples. This test does not detect other chromosome abnormalities.

How is the result reported?

- ▶ Most results are either low risk (<1/10,000) or high risk (>99%). Fewer than 1% of results will have an intermediate numerical risk (for example 1 in 100). In 5-10% of samples a result cannot be obtained and a redraw is requested.

Does a low risk result mean the fetus does not have Down syndrome, trisomy 18, trisomy 13 or a sex chromosome abnormality?

- ▶ No. This is a new test with limited data. A low risk result significantly reduces the risk of these conditions, but the test is not considered diagnostic. Validation studies for sex chromosome abnormalities and gender determination have not been published.

What is recommended after a test result indicates high risk?

- ▶ Diagnostic testing such as CVS between 11-14 weeks, or amniocentesis after 15 weeks is recommended to confirm a diagnosis.

When can this test be done?

- ▶ Any time on or after 10 weeks 0 days in a singleton pregnancy.

When are results available?

- ▶ 10-14 days. Results are communicated directly to a genetic counselor who will then call the patient with the result.

Does insurance cover this test?

- ▶ The list price for the test is \$795. With the addition screening for the X and Y chromosomes, the price is \$815.
- ▶ Unfortunately, we have no information about whether insurance companies will cover the cost or the amount of coverage. We strongly recommend that the patient contact her insurance provider directly to determine coverage, including deductibles and co-pays. Please provide the following information:

Name of lab: Esoterix Genetic Laboratories, LLC, Monrovia (California)

National Provider Identifier #: 1922309376

Ordering physician: Louanne Hudgins, MD

- ▶ CPT Code: 81599
- ▶ ICD9 Code: _____