If I am High Risk, what additional testing is available?

If a Harmony Prenatal Test shows you are High Risk, it does not necessarily mean that the pregnancy has one of these birth defects. Your healthcare provider may offer you one of the following procedures:

- **Chorionic villi sampling (CVS)** is a procedure that takes a small amount of tissue from the developing placenta. The tissue is then sent to a laboratory to test the chromosomes. CVS is typically performed between 10 and 12 weeks of pregnancy. CVS is associated with a small risk of miscarriage.
- **Amniocentesis** is a procedure that withdraws a small amount of fluid that surrounds the fetus. The fluid is then sent to the laboratory to test the chromosomes. An amniocentesis is usually performed around or after the 16th week of pregnancy. Amniocentesis is associated with a small risk of miscarriage.

Harmony Prenatal Test does not screen for open neural tube defects. Open neural tube defects occur when the baby's neural tube does not close completely and an opening remains along part of the baby's spine or head. Open neural tube defects occur in about 1 out of every 1,500 live births.[6] A second trimester blood test called MSAFP, or an ultrasound, is required to detect open neural tube defects.

The Harmony Prenatal Test has been developed and is performed as a laboratory test service by Ariosa Diagnostics, a CLIA-certified clinical laboratory.

References

1. U.S. National Library of Medicine. Genetics Home Reference. Down Syndrome. http://ghr.nlm.nih.gov/condition/downsyndrome. Accessed July 12, 2012.
2. U.S. National Library of Medicine. Genetics Home Reference. Trisomy 18. http://ghr.nlm.nih.gov/condition/trisomy-18. Accessed July 12, 2012.
3. U.S. National Library of Medicine. Genetics Home Reference. Trisomy 13. http://ghr.nlm.nih.gov/condition/trisomy-13. Accessed July 12, 2012.
4. ACOG Practice Bulletin 77. Screening for fetal chromosomal abnormalities. Obstet Gynecol. (2007) 109:217–227.
5. Norton, M., Brar, H., Weiss, J., Karimi, A., et al. Non-Invasive Chromosomal Evaluation (NICE) Study: Results of a Multicenter, Prospective, Cohort Study for Detection of Fetal Trisomy 21 and Trisomy 18, *Am J Obstet Gynecol.* (2012), doi:10.1016/j.ajog.2012.05.021.
6. U.S. Food and Drug Administration (FDA). http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm192649.htm. Accessed July 18, 2012.

About Integrated Genetics

Integrated Genetics has been a leader in genetic testing and counseling services for over 25 years.

About Ariosa Diagnostics

Ariosa Diagnostics, Inc. is committed to providing safe, highly accurate and affordable prenatal tests for maternal and fetal health.

This brochure is provided by Integrated Genetics and Ariosa Diagnostics, Inc. as an educational service for health care providers and their patients.

For more information on our genetic testing and counseling services, please visit our web sites:

www.harmonytest.com
www.mytestingoptions.com
www.integratedgenetics.com

For billing information, please call 800-845-6167.

We are available between the hours of 8:00 AM to 5:00 PM, Monday through Friday.

Ariosa™ DIAGNOSTICS

Integrated GENETICS
LabCorp Specialty Testing Group

rep-616-v2-0812

Integrated Genetics Client Services
(800) 848-4436

Harmony™ PRENATAL TEST

An advance in non-invasive fetal trisomy testing

Ariosa™ DIAGNOSTICS

Integrated GENETICS
LabCorp Specialty Testing Group

Harmony Prenatal Test

Simple, safe and accurate for you and your pregnancy.

The Harmony™ Prenatal Test is a non-invasive test that detects common fetal trisomies in pregnancies of 10 weeks or more, based on directed analysis of DNA in maternal blood.

What is a trisomy?

Humans have 23 pairs of chromosomes, which are strands of DNA and proteins that carry genetic information. A trisomy is a chromosomal condition that occurs when there are three copies of a particular chromosome instead of the expected two.

Trisomy 21 is due to an extra chromosome 21 and is the most common trisomy at the time of birth. Trisomy 21, also called Down Syndrome, is associated with mild to moderate intellectual disabilities and may also lead to digestive disease and congenital heart defects.[1] It is estimated that trisomy 21 is present in 1 out of every 700 newborns.[1]

Trisomy 18 is due to an extra chromosome 18. Trisomy 18, also called Edwards Syndrome, is associated with a high rate of miscarriage. Infants born with trisomy 18 often have congenital heart defects as well as various other medical conditions, shortening their lifespan. It is estimated that trisomy 18 is present in approximately 1 out of every 5,000 newborns.[2]

Trisomy 13 is due to an extra chromosome 13. Trisomy 13, also called Patau Syndrome, is associated with a high rate of miscarriage. Infants born with trisomy 13 usually have severe congenital heart defects and other medical conditions. Survival beyond the first year is rare. It is estimated that trisomy 13 is present in approximately 1 out of every 16,000 newborns.[3]

Harmony detects trisomies of chromosomes 21, 18 and 13 in the fetus, but does not rule out all fetal abnormalities.

What will the Harmony Prenatal Test tell me and my healthcare provider?

The Harmony Prenatal Test assesses the risk of three fetal trisomies by measuring the relative amount of chromosomes in maternal blood.

How is the Harmony Prenatal Test different from other prenatal tests?

The Harmony Prenatal Test is based on the newest advances in non-invasive prenatal testing. It is a simple and safe blood test that has been shown in clinical studies to detect the risk of fetal trisomies with high accuracy.[4]

The Harmony Test has been shown to have detection rates of up to 99% and false positive rates as low as 0.1% for trisomy 21, 18 and 13. Diagnostic tests such as amniocentesis or chorionic villus sampling (CVS) are accurate for detecting fetal trisomies, but they are invasive and pose a slight risk for fetal loss.[5]

Who can get the Harmony Prenatal Test?

The Harmony Prenatal Test can be ordered by healthcare professionals for women with pregnancies of at least 10 weeks' gestational age. The test is not for use in multiple pregnancies (such as twins) or egg-donor pregnancies.

Low Risk result

If the Harmony Prenatal Test results show a Low Risk, the chance of having a baby with trisomy 21, trisomy 18, or trisomy 13 is low. As with any test, a low risk result reduces, but does not eliminate, the chance of having an affected pregnancy.

High Risk result

If the Harmony Prenatal Test results show a High Risk, there is an increased chance of having a baby with trisomy 21, trisomy 18, or trisomy 13. If your result is High Risk, your healthcare provider may offer genetic counseling and/or diagnostic testing to determine if your baby is affected with one of these conditions.

Ask your provider

The information in this brochure is provided to inform you about the Harmony Prenatal Test. Talk to your healthcare provider before you decide if the Harmony Prenatal Test is appropriate for you.