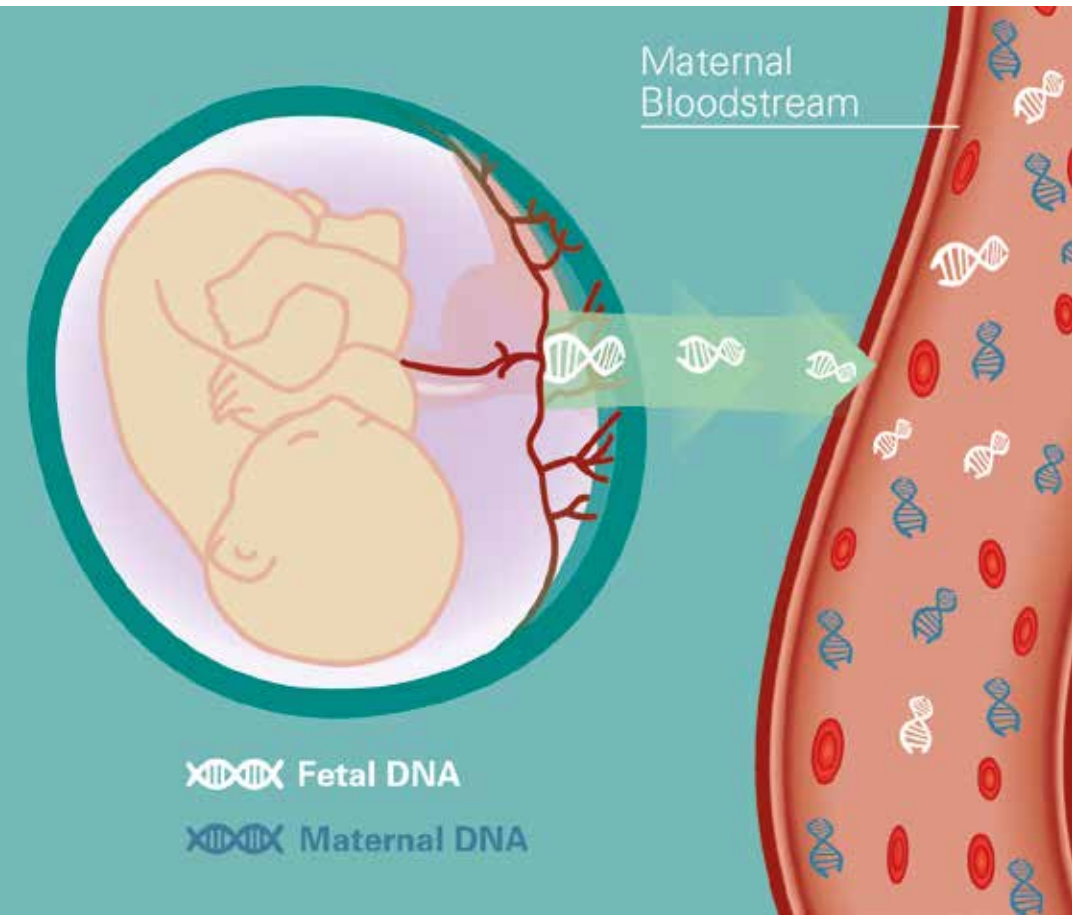
Better prenatal testing for everyone

Ariosa Diagnostics, Inc. has developed leading-edge technologies to perform a directed analysis of cell-free DNA in blood. It is the company behind the HarmonyTM Prenatal Test, a non-invasive blood test for pregnant women that can be used as early as 10 weeks into pregnancy. By evaluating cell-free DNA found in maternal blood, the test can assess the risk of Trisomy 21 (Down syndrome) in the foetus as well as certain other genetic conditions. It is available in more than 90 countries and has been used to guide clinical care in over 325,000 pregnancies worldwide.

Dr. Song is one of the co-founders of Ariosa. Prior to Ariosa, he was an investor at Venrock and led multiple investments in healthcare companies. In that capacity, he came across the prenatal testing space and brought together a team that developed the proprietary technology behind the Harmony test. He explains that Ariosa's goal since inception has been to meet the demand for both highly accurate and affordable genetic testing, with an initial focus on prenatal testing. Ariosa builds on the fairly recent scientific development of a blood-sample-based test that can assess the risk of whether a foetus has an underlying genetic condition like Down syndrome with high accuracy. Scientists discovered cell-free DNA outside of the cell floating in the mother's bloodstream, for both the mother as well as the foetus. What makes Ariosa's test unique is that it takes a more targeted or directed approach to looking at the DNA, resulting in significantly higher efficacy, quality and value.

Dr. Song believes that the main benefit of the Harmony Prenatal Test developed by Ariosa, is that it helps to prevent unnecessary invasive procedures associated with high rates of false positive results from conventional screening tests. "To put this into perspective: each year in the United States, up to a couple of thousand babies are lost as a result of unnecessary invasive procedures," he explains. "About six million women get pregnant each year in the US. Many of those women undergo prenatal screening to test for genetic conditions such as Trisomy 21, which causes Down syndrome. The conventional blood test and ultrasound combination often used for such testing have roughly a 5% false positive rate. Many women with these false alarms subsequently undergo a diagnostic invasive procedure, such as amniocentesis, that uses a lengthy needle that subjects both the mother and foetus to significant risk." Invasive procedures can cause a miscarriage in as frequent as 1 in 100 procedures.

Several prenatal diagnostics firms have popped up over the past years to address the problem by using DNA sequencing to improve the safety and accuracy of the tests. Among them,



Harmony Prenatal Test relies on a proprietary targeted DNA-based technology to provide exceptionally accurate results.

- *Cell-free DNA—short DNA fragments—of the mother and the fetus circulate in maternal bloodstream during pregnancy*
- *Harmony analyzes fragments from specific chromosomes, rather than all chromosomes*

Harmony by Ariosa Diagnostics is both highly accurate and widely accessible, delivering true value to the patient, says Dr. Song. "The false positive rate of our test is less than 0.1%. That's at least 50 times lower than the current false positive rate for traditional screening tests."

While Harmony assesses risk of Trisomy 21, the test also screens for other rarer genetic conditions, says Dr. Song. All tests are currently done at Ariosa's labs in the US. Ariosa's customers range from clinics to clinicians, while the company also partners with other labs as well as with hospitals. Ariosa started testing in mid 2012 and by early October 2014 had tested over 325,000 women.

Recently, Ariosa's own scientists have successfully validated a microarray DNA quantification method for Ariosa's Harmony test. The advantages of microarray over next generation sequencing include shorter turn-around time, better measurement accuracy, and lower cost. Microarrays have also been used extensively for many years in prenatal testing and it is a more robust and stable method compared to next generation sequencing. The results were published online in Foetal Diagnosis a nd Therapy. This technological advancement in NIPT was innovated by Ariosa scientists as part of a long term vision to enhance performance and reduce turnaround time for patients to receive results from this type of test.

Harmony has been validated with the largest clinical data set in the prenatal cell-free DNA space, making it the most broadly studied cell-free DNA test. Dr. Song says that blinded prospective studies underscoring the efficacy of Harmony are published in over 15 peer-reviewed publications. Efficacy of the test for the general population of pregnant women, notably, was supported in a study of 2049 pregnant women in collaboration with Professor Kypros Nicolaides at the Fetal Medicine Center in the UK. The study was published in the American Journal of Obstetrics and Gynaecology at the end of 2012. Since then, Ariosa has published additional clinical data and recently completed a landmark study, the NEXT study, which involved nearly 19,000 women representing a general pregnancy population cohort. These studies specifically address the accuracy of the Harmony test for any pregnant woman, regardless of age or perceived risk of having a baby with a genetic condition.

"Given that 130 million women give birth every year, we are still at the very early stages of adoption of our test," says Dr. Song. "Our view is that given that Harmony is clearly a better test than anything else that is on the market today, all pregnant women should have access to it. That is our mission really. To make it the standard of care, in other words to ensure that all pregnant women get the test as a standard procedure, and not just women who are considered high-risk."

Ariosa™
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