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TRANSCRIPT

Transcript Details
This is a transcript of an educational program accessible on the ReachMD network. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/what-sets-harmony-prenatal-test-apart-other-cell-free-dna-screening-tests/10363/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

What Sets the Harmony Prenatal Test Apart from Other Cell-Free DNA Screening Tests?

Announcer: Welcome to ReachMD. The following program: “What Sets the Harmony Prenatal Test Apart from Other Cell-Free DNA Screening Tests?” is sponsored by Roche Diagnostics.

Roche Narrator: Thanks to rapid advances in genetic testing, many self-free DNA prenatal screening tests are available to you and your patient today. At Roche, we believe in offering a high-quality test with a clinically relevant and meaningful test menu that will bring confidence to your practice and piece of mind to your patient. The Harmony prenatal test is a noninvasive prenatal test available as early as 10 weeks gestation. It analyzes cell-free DNA in maternal blood to screen for specific chromosome conditions in the pregnancy. The changes associated with these conditions can be life altering, that is why the Harmony prenatal test is designed with comprehensive quality metrics to ensure a reliable result. One very important quality metric for the Harmony test is called fetal fraction. During pregnancy small pieces of DNA from both mother, baby, and placenta are present in the mother’s blood. These pieces are called cell-free DNA and the portion that comes from the baby and placenta is called the fetal fraction.

A publication using 22,000 Harmony prenatal test samples have shown that fetal fraction increases with gestational age and decreases with maternal weight. Some studies have suggest that also fetal fraction

decreases in some aneuploidies. If fetal fraction is not incorporated in the assessment of a trisomy then potentially only the maternal portion is analyzed and without the baby, thereby leading to potential false negatives or discording calls. Professional societies like the International Society for Prenatal Diagnosis, ACOG, and ACMG has included statements and information on the importance of measuring fetal fraction in a prenatal test. The Harmony prenatal test adheres to the ACMG guidelines by disclosing the fetal fraction values for each sample on the test report form so that clinicians and expecting parents can trust the result.

Other prenatal self-free DNA based tests may also measure and report fetal fraction. However very little is known and published regarding the accuracy and reproducibility of those methods.

At Roche, we've conducted a recent study involving greater than 47,500 clinical samples where we've compared the fetal fraction measurements from the Harmony tests to that of chromosome y quantitation. The result shows the two methods are highly concordant with the Pearson correlation of 0.97. In the same study we've also performed reproducibility analysis, where two tubes were drawn from the same patient and followed for 3 months where the analysis of tube one and tube two could span as long as 3 months. In that period the analysis of these tubes involved multiple reagents, multiple operators, multiple robots, and is truly an assessment of how reproducible fetal fraction is across the two tubes. The result was also a very high concordant of Pearson correlation coefficient of 0.98. The Harmony test was originally conceived and really designed to reduce unnecessary invasive testing, reduce unnecessary anxieties for expecting parents and it is, I will say by far, a test that was designed to do what it's supposed to do.

Announcer: The preceding program was brought to you by Roche Diagnostics. This is ReachMD. Be Part of the Knowledge.