MEDICAL POLICY FOR NONINVASIVE PRENATAL TESTING FOR FETAL ANEUPLOIDY (NIPT)

Noninvasive prenatal testing uses cell free fetal DNA from the plasma of pregnant women processed through a technology known as massively parallel genomic sequencing to detect trisomy 13, trisomy 18 and trisomy 21 as early as the 10th week of pregnancy. Because this is a simple blood draw for the mother, it is considered a safe, noninvasive test compared to invasive testing of chorionic villus sampling (CVS) or amniocentesis.

Detection rates for trisomy 13, 18 and 21 are greater than 98% with very low false positive rates (less than 0.5%).

The American College of Obstetricians and Gynecologists (ACOG) have set forth recommendations regarding prenatal assessment and these recommendations have been adopted by the Ventura County Health Care Plan.

1. Primary prenatal screening, consisting of ultrasound for nuchal translucency and alpha fetoprotein testing, is to be offered to all pregnant women at fetal gestational age between 10 and 13 weeks for blood test and between 11 and 14 weeks for ultrasound.
2. Cell free fetal DNA testing is an option for a primary screening test for women at increased risk of aneuploidy and should be offered for the following:
    a. Women aged 35 years or older
    b. Fetuses with ultrasonographic findings that indicate an increased risk of aneuploidy
    c. Women with a history of a child affected with a trisomy
3. Cell free fetal DNA testing can also be used as a follow-up test for women with positive first-trimester or second-trimester screening test result.

Cell free fetal DNA testing is not currently recommended for low-risk populations or for multiple gestations.

Note that cell free fetal DNA testing does not replace the precision obtained with CVS or amniocentesis, and currently does not offer other genetic information.

After review of the presently available diagnostic tests for NIPT, VCHCP will approve the trademarked Informaseq test when the above guidelines are met. The blood is drawn at a VCHCP contracted lab and picked up by Lab Corp or Integrated Genetics. Turnaround time is less than 7 business days.

Exclusions: Cell free fetal DNA testing is not approved for gender identification.

A. History:

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