Clinician Guide to Results

The Panorama test is a non-invasive prenatal screening test (NIPT) that uses SNP technology to calculate pregnancy-specific risks for common chromosomal aneuploidies. In certain circumstances, a patient's result may state "*unable to report.*" Below are details to help with the understanding of possible causes of these types of results.

Unable to Report – Redraw Recommended

A redraw will be recommended when we believe the issue was likely specific to the DNA fragments from the particular sample, and a subsequent sample would help yield more accurate results. Although all of the reasons behind low fetal fraction have not been investigated at this time, these results do not indicate a risk for any particular problem in the pregnancy. The redraw recommendation is in place in order to assure accuracy when results are achieved. Approximately 85% of the women who are recommended for redraw will receive a result on their second draw. Other companies prefer to report out on all samples, even when borderline or unclear, and run the risk of lower sensitivity and specificity with their results.

LOW FETAL FRACTION – when the fetal cfDNA percentage is extremely low (<3.5%), we are unable to obtain high confidence results from the algorithm. (Please note: Most other NIPT methods have a fetal fraction cutoff of 4%)

DOES NOT PASS QUALITY METRICS -- The DNA analyzed in some samples is inherently less informative ("noisy" data), making it difficult for the algorithm to obtain a high confidence result. These metrics include total DNA amount (maternal and fetal DNA combined), number of reads, and other control metrics that are in place to ensure good quality data for accurate, consistent results.

Unable to Report – Uninformative DNA Pattern - Redraw Not Recommended

Although the majority of our inability to report on an initial sample will be issued along with a recommendation for redraw, there are rare cases (<1%) that a second sample is not requested. These are situations in which the DNA of a particular individual (mother or fetus) is not able to be interpreted as necessary for this test. The most likely causes of this are conditions of pregnancy that are not yet validated for our test (e.g. egg donor pregnancies, pregnancies achieved with surrogacy, and multiple gestations). Other reasons can include: vanishing twin pregnancies (where there is contribution of a second fetal DNA pattern), fetal mosaicism on chromosomes tested, maternal chromosomal abnormalities or mosaicism on chromosomes tested, and higher than expected levels of homozygosity on the chromosomes tested (when the SNPs between mom and baby are too similar to yield informative results, possibly from consanguinity, segmental uniparental disomy, or simply chance). Review of clinical history, additional follow-up testing or both may be recommended in order to better assess further testing options for this patient.

Partial Results

Occasionally, only one of the chromosomes analyzed is not able to be reported. These will have a high/low risk score designated for most of the chromosomes analyzed, while one (or more) chromosome(s) will be "no results". This can be due to the "uninformative DNA pattern" or "failure to pass quality metrics" on that chromosome alone and redraws will be recommended when appropriate. Any redraw that is recommended and obtained will be reanalyzed for all chromosomes.

Results Consistent with the Presence of Triploidy or Multiple Gestations –

Although these results increase the risk for a triploid fetus, the possibility of a multiple gestation or vanishing twin pregnancy cannot be excluded due to the similarity of SNP results in these three clinical situations. Review of clinical history along with ultrasound findings and possible diagnostic prenatal testing is recommended to fully interpret results.

This test was developed by Natera, Inc., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

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