**Why report a risk score?**

At Natera, we are committed to providing you and your patients with accurate, responsible reporting. Panorama, like other non-invasive prenatal tests (NIPTs), is an advanced screening test used to determine which pregnancies are at high risk and low risk for certain chromosome conditions. It is recommended that all women with a high risk result have genetic counseling and diagnostic testing for confirmation of NIPT results, per ACOG committee opinion #545. By providing your patient with a Panorama personalized risk score that is based upon her baby’s specific DNA pattern, you can ensure high quality, accurate result reporting.

While some NIPT laboratories report a simple positive or negative result, it is important to realize that NIPT is not a diagnostic test. Positive/negative reporting can be confusing and misleading to the patient in this scenario because a positive result indicates a significantly increased risk for chromosome abnormality, but does not necessarily mean the fetus is affected. A negative result does not exclude the possibility that the fetus is affected. By assigning a numerical risk score, Panorama avoids this confusion and provides a true representation of the possibility of fetal chromosome abnormality.

**How is the risk score calculated?**

Unlike other NIPTs, Panorama SNP technology can separate and analyze the maternal and fetal cell free DNA sequences (SNPs) found in maternal blood. Analysis of the SNPs determines the most accurate and highest confidence result for the fetus. In order to ensure a high confidence result, many factors, such as fetal fraction, total DNA amount, quality of DNA fragments, number of SNPs analyzed per chromosome, and others, are assessed. The final risk calculation incorporates the patient’s maternal age risk for the chromosome condition (her a priori risk) with the results from the SNP analysis. The advantage of SNP technology is that, unlike other NIPTs, the final Panorama risk score is based upon the patient’s specific SNP analysis and not on a generalized test sensitivity and specificity. This means each patient will receive a personalized risk score, which can assist both you and the patient make decisions regarding further prenatal testing.

**How will the risk score be reported?**

About 99% of patients will receive a risk score of <1/10,000 or >99/100, which are the two extremes of the risk range. However, 1% of patients may have risk score that falls between these two extremes. This is because there are many quality metrics, including fetal fraction, total DNA amount, quality of DNA fragments and number of SNPs analyzed, that must be met in order to ensure high confidence results. How well these metrics are met will ultimately impact the final risk score. For example, if two women of the same maternal age and gestational age have their blood drawn and one has a fetal fraction of 4% with the minimum required SNPs analyzed while the other has a fetal fraction of 15% with more than the minimum SNPs analyzed, they will have different risk scores that is based on the data their DNA generated.

A risk score of 1 in 100 or greater is interpreted as a HIGH RISK result. A risk score less than 1 in 100 is interpreted as a LOW RISK result. This particular cut-off was selected as the most appropriate after thorough review of Panorama validation data and extensive discussions with key opinion leaders in prenatal diagnosis.

The tests were developed by Natera, Inc., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). These tests have not been cleared or approved by the U.S. Food and Drug Administration (FDA).