

Why is Panorama testing sometimes unable to provide a result?

Panorama is a non-invasive prenatal screening test (NIPT) that uses advanced DNA technology to provide pregnant women with a more accurate idea of their risks for having a baby with certain types of genetic conditions. Sometimes, a patient's result report may come back as "unable to report." Below are the reasons as to why this might happen:

Unable to Report—Redraw Recommended

• **Report Indicates: "Low fetal fraction":** Panorama works by looking at fetal DNA that is found in the pregnant mother's blood. On average, 10% of the DNA in the mother's blood is from the fetus (i.e. 10% fetal fraction) and 90% is from mother. However, the percentage of DNA that is from the fetus can range from 1% to 30% and can be different from day to day even in the same pregnancy. The higher the percentage of fetal DNA, the easier it is to get results, and when it is lower it can be more difficult. When you are told there is a low fetal fraction, it does NOT mean we found a problem with the baby; it just means that the amount of fetal DNA in that sample is too low for the test to get accurate results. No NIPT test is accurate below 3.5%. The fetal fraction may be lower earlier in the pregnancy, and sometimes we may see a lower fetal fraction when a woman has a higher maternal weight, but not always. Another blood draw at a later week of pregnancy may have more fetal DNA so that we can get a high quality result. There are rare cases when the fetal fraction will stay low, even with a second blood draw. We do not always understand the reason for this, and a woman may want to discuss alternative forms of screening or testing with her doctor. *(This is a no result for all conditions).*

• **Report Indicates: "Failed Quality Metrics"** Each blood specimen that comes to the Natera Laboratory for Panorama testing, must pass a series of tests (also called quality metrics) to ensure that there is enough DNA to study and that the quality of DNA is high enough to get an accurate result. If the blood specimen fails a quality metric, the laboratory will send a report to the patient's doctor requesting another sample of blood be submitted for analysis. A failed quality metric does NOT mean there is an abnormality. It simply means the laboratory would like another sample. Patients and their doctors can feel very confident that Panorama will only give them results that are both high quality and accurate. *(This can be no result for a single genetic condition or no result for all of the conditions.)*

Unable to Report—Redraw NOT Recommended

Report Indicates: "Unable to report due to uninformative DNA pattern": As human beings, we all have slight differences in our DNA. Sometimes the differences can affect the ability to get an accurate test result with Panorama. It is uncommon for these differences in DNA to be associated with health issues, and most likely they are considered to be "normal variations". In rare situations, the DNA between a woman and her baby are very similar, which can make it hard to give accurate results on the baby alone. If a woman is pregnant with more than one baby, if she is carrying a pregnancy conceived with the use of an egg donor or surrogate mother, if she had a bone marrow transplant at some point in her past, or if the parents or maternal grandparents of the pregnancy are closely related to one another, the DNA pattern will prevent Panorama from getting accurate results. When redraw of blood is NOT recommended, it simply means that we would not expect another blood sample to be helpful or to provide a result because DNA patterns do not change. In such situations, a woman may want to discuss alternative forms of screening or testing with her doctor. *(This can be no result for a single genetic condition or no result for all of the conditions.)*

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).