

QNatal® Advanced, Non-Invasive Prenatal Screening INFORMED CONSENT

1. What is QNatal® Advanced? QNatal® Advanced is a screening test that provides information about your fetus' chance of having chromosomal abnormalities associated with Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), and Patau syndrome (trisomy 13). In addition, QNatal® Advanced will also report an increased risk for conditions involving the sex chromosomes (monosomy X, XXX, XXY, and XYY) and microdeletion syndromes when requested. This test uses fetal DNA found in your blood to assess the risk that the fetus may have one of these chromosomal abnormalities.

2. What is the purpose of this test and what are its limitations? QNatal® Advanced is a screening option to estimate risk for specific chromosomal abnormalities in your fetus. This may be offered to you due to your age, suggestive ultrasound findings, positive maternal serum screening result, or other reasons outlined by your physician. The test analyzes DNA from the placenta in the maternal blood to estimate the risk that the fetus may have one of the chromosomal abnormalities. The DNA from the placenta is usually representative of the fetus. Occasionally, the test is unable to estimate the risk for one or all of the abnormalities. This may be due either to the specific sample or other confounding factors. In addition, the test results may be unclear due to mosaicism (a condition in which cells within the same person have a different genetic makeup) or a health condition present in you. In those cases, the report will indicate if a redraw is recommended. In addition, occasionally there will not be enough placental DNA in your sample and you will be asked to have a new sample drawn. You may elect to see a professionally-trained genetic counselor prior to signing this informed consent form.

3. What does a negative test result mean? A negative result means that the fetus probably does not have one of these chromosomal abnormalities. However, a negative result does not guarantee the birth of a healthy baby without these abnormalities. Additionally, neural tube defects, other birth defects, and other causes of intellectual disability are not detectable by QNatal® Advanced.

4. What does a positive test result mean? A positive result means that the fetus has a high chance of having that chromosomal abnormality. Further testing procedures are needed to confirm the result, including: chorionic villi sampling, amniocentesis, targeted ultrasound or blood testing on you. Your health care provider can help you understand the risk, provide information about the suspected chromosomal abnormality, and explain the additional tests that may be recommended and are available.

5. What is required to perform this test? You will be asked to provide 20 mL (2 tubes) of blood. DNA from you and DNA from the placenta will be extracted from your blood sample and tested. The only discomfort that you may feel is the stick of the needle in your arm. You may also experience a small bruise at the site of the needle puncture. You may be asked to provide information regarding your personal and family medical history when necessary for proper interpretation of your test result. In the unlikely event that you should be injured in the course of being tested, your physician will provide any necessary medical care. However, you would be expected to bear the cost of such medical care. Compensation will not be provided in the event of any injury.

6. Is there a cost for this test? This is a clinical laboratory test and the results may aid in your care; thus, you or your health insurer will be billed for this screening.

7. What will happen to the DNA once the test is complete? The original blood sample will be discarded at the end of the testing process or stored for not more than 30 days. In some circumstances, your DNA may be used anonymously as a negative or positive control sample in future testing for up to 6 months. But, in this circumstance, all identifiers will be removed prior to re-testing and the DNA sample and results obtained will remain anonymous.

I understand and agree that my DNA remaining after testing may be stored without identifiers for up to 6 months. Please initial. _____

I understand and do not want my DNA stored or used for any other testing. Please initial. _____

8. How will I obtain results from this test? Genetic testing and interpretation of results are complex. The information from this test will be provided in the form of a written report to your physician, who will inform you of the results. Results are available to you through the MyQuest™ by Care360® app or through written request from your local Quest Diagnostics laboratory. Your physician may suggest genetic counseling prior to performing this test or if your results are abnormal. If you receive a positive test result, then you may want to consider having more tests done, speaking to your physician, or seeing a genetic counselor to discuss your results. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without your written authorization.

Patient Attestation of Informed Consent:

My signature below indicates that I have received information about this screening test, QNatal® Advanced, and that I have read and understood the material in this document. I have been given full opportunity to ask any questions that I may have about the testing procedure and related issues. I agree to undergo this testing.

Signature of Patient

Date

For the Physician:

As the referring physician, I understand the benefits and limitations of this study and have requested that the above-named patient be tested. I attest to the fact that I have provided the patient with the information contained above and fully answered any questions. I believe that the patient understands the information and is voluntarily signing this informed consent.

Signature of Physician/Health Care Professional

Print Name of Physician/Health Care Professional