Alpha Labs

QNatal®Advanced - Non-Invasive Prenatal Screening (NIPT) Test Requisition

For Fetal Chromosomal Abnormalities as early as 10 weeks gestation

PATIENT INFORMATION

Last Name: _____

First Name: _____

Date of Birth: _____ mm/dd/yy

Sex: ☐ F ☐ M

Address: _____
No. Street Apt

_____
City Province Postal Code

Tel: _____

CLINICAL INFORMATION (REQUIRED)

☐ DO NOT report (opt out) for microdeletions (subchromosomal copy variant)

☐ DO NOT report (opt out) for fetal sex

Patient's estimated Due Date: _____ mm/dd/yy
(must be at least 10 weeks gestation)

Maternal weight: ☐ Kg ☐ Lbs; Maternal height: _____ Ft. _____ In.

Number of Fetuses: ☐ 1 ☐ 2

Vanishing twin: ☐ Yes ☐ No

LMP date, or IVF Transfer date: _____ mm/dd/yy

IVF pregnancy: ☐ Yes ☐ No (If Yes Egg Age at retrieval _____ years.)

MEDICAL INDICATION FOR TESTING (select all that apply)

☐ Advanced Maternal Age ☐ Abnormal MSS serum screen ☐ Ultrasound findings

☐ Pregnancy history ☐ Family history

☐ Other (please specify) _____

PATIENT ATTESTATION AND INFORMED CONSENT

My signature below indicates that I have received, read (or have had read to me) and understand the information about QNatal® Advanced Non-Invasive Prenatal Test and that I have been given full opportunity to ask questions and discuss limitations, reliability and possible risks of the test with my healthcare provider(s). I understand I must sign this informed consent form in order for the test to be performed and **acknowledge that I am responsible for the full payment $415.00 for this private pay test at the time sample collection**.

Patient Signature: _____

Date: _____ mm/dd/yy

SAMPLE COLLECTION INFORMATION

Blood draw: 10ml Steck cell free DNA (CFDNA) tube

Collection date: _____ mm/dd/yy

Collection time: _____ hh/mm

Collector Name: _____

Redraw: ☐ Yes ☐ No

IMPORTANT Sample must be kept at room temperature at all times.
DO NOT REFRIGERATE

ORDERING CLINICIAN INFORMATION

Last Name: _____

First Name: _____

Clinic: _____

Address: _____
No. Street Apt

_____
City Province Postal Code

Tel: _____

Fax: _____

COPY TO OTHER HEALTHCARE PROVIDER

Last Name: _____

First Name: _____

Address: _____
No. Street Apt

_____
City Province Postal Code

Tel: _____

ORDERING CLINICIAN SIGNATURE

As the referring clinician, I understand the benefits and limitations of QNatal® Advanced NIPT and have requested the above patient be tested. I attest that I have provided the patient with the required information including the limitations and risks of this test and have fully answered any questions. I believe the patient understands the information and has given fully informed and voluntary consent for this test.

Clinician Signature: _____

Date: _____ mm/dd/yy

FOR LAB USE ONLY

Date sample received: _____ mm/dd/yy _____ AM/PM

Received by: _____

LAB BARCODE

Alpha Labs 1262 Don Mills Rd., Toronto, Ontario M3B 2W7 Tel: 416.449.2166 Fax: 416.449.2543
Customer Support: email customersupport@alphalabs.ca

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 10 mL (1 tube) 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.

6. **Is there a cost for this test?** This is a clinical laboratory test and the results may aid in your care. I understand and agree that I am required to pay $415.00 for the test at the time of sample collection in order for the test to be processed.

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. 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