EARLY REVEAL™

EARLYREVEAL™ NIPT Test
Powered by Illumina Technology

NONINVASIVE PRENATAL TEST REQUISITION FORM

***Required information.**

PATIENT INFORMATION:

Last name:* **First name:*** MI: **DOB:*** M M / D D / Y Y Y Y

Sex: Female Medical Record #: Client sample ID:

Address: Email : Phone number:

City/Province: Country: ZIP:

ACCOUNT/ORDERING PROVIDER*:

Health care provider: 140 Genetic counselor:

Account name: EARLYREVEAL -DV Account #:

ADDITIONAL REPORTING TO:

Authorized health care provider: Address:

CLINICAL INFORMATION:

Gestational age:* Weeks: Days: As estimated on M M / D D / Y Y Y Y **Date of draw:*** M M / D D / Y Y Y Y

Maternal height: ☐ cm ☐ ft in Maternal weight: ☐ kgs ☐ lbs

DATING METHOD (MUST CHOOSE ONE):*

☐ LMP ☐ Date of implantation ☐ CRL

☐ Other Specify:

CHOOSE ONE NIPT TEST AND ALL OPTIONS THAT APPLY):*

EarlyReveal Prenatal Test (chromosomes 21, 18, 13)

☐ Singleton

Additional option:

☐ Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)

☐ Twin

Additional option:

☐ Presence of Y chromosome

OR

EarlyReveal Prenatal Test (chromosomes 21, 18, 13)

Singleton

Additional options:

☐ Microdeletions:
1p36 deletion, 4p- (Wolf-Hirschhorn syndrome), 5p- (cri-du-chat syndrome), 15q11.2 (Prader-Willi syndrome/ Angelman syndrome), 22q11.2 deletion (DiGeorge syndrome)

☐ Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)

☐ All chromosomes including sex chromosome aneuploidies [MX, XXX, XXY, and XYY])

TEST INDICATIONS (CHOOSE AT LEAST ONE) :

☐ Advanced maternal age (≥ 35 years)
☐ Positive serum screen
☐ Abnormal ultrasound
☐ History suggestive of increased risk for the specified chromosome aneuploidies
☐ Low risk/maternal anxiety
☐ Other

Comments:

I certify that (i) this test is medically indicated, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law and EarlyReveal's Patient Informed Consent. I agree to provide EarlyReveal, or its designee, any and all additional information reasonably required for this testing to be performed.

Health care provider signature:* **Date:**

PATIENT CONSENT: By signing this form, I, the patient having this screening performed, acknowledge that: (i) I have been offered the opportunity to ask questions and discuss with my health care provider the benefits, risks, and limitations of the test to be performed; (ii) I have discussed the test limitations (reliability of positive and negative test results; the predictive value of the test results; and that the test is not a diagnostic test, but a screening test and is not definitive) with the health care provider who ordered the test; (iii) I have been informed about the availability and importance of genetic counseling and have been provided with information identifying an appropriate health care provider from whom I might obtain such counseling; (iv) I have received, read, and understood the Patient Informed Consent in its entirety and that I may retain a copy for my records; (v) I consent to the use of the leftover specimen and health information as described in the Patient Informed Consent; (vi) I consent to having this test performed; and (vii) I will discuss the results and appropriate medical management with my health care provider.

Patient signature: **Date:**

Non-invasive prenatal testing (NIPT) based on cell-free DNA analysis from maternal blood is a screening test. Screening tests are not diagnostic or definitive.
Because there is a small possibility that a screening result might be incorrect, it is important to talk to your physician to determine if further testing is needed.
EarlyReveal NIPT is validated for singleton and twin pregnancies and EarlyReveal NIPT Plus is validated for singleton pregnancies with gestational age of at least 10 weeks 0 days.

Patient informed consent

OBJECTIVE

EarlyReveal's non-invasive cell-free DNA prenatal screening is designed to determine the risk of detecting certain chromosomal abnormalities in your fetus(es). This screening is valid for single and twin pregnancies over 10 0/7 weeks of amenorrhea.

- Trisomy 13-18 and 21 screening (single and twin pregnancies)
- Detection of Y chromosome/fetal sex (single and twin pregnancies)
- The following sex chromosome anomalies: Turner (MX), Klinefelter (XXY), Jacob (XYY) and fetal sex (single pregnancies) *
- Risk of trisomies on all 23 chromosome pairs (single pregnancies) *
- The following microdeletions: Deletion 1p36; 4 p (Wolf-Hirschhorn); Monosomy 5p; 15q11.2 (Prader-Willi/Angelman); Deletion 22q11.1 (DiGeorge) (singleton pregnancies)* (singleton pregnancies).

*These additional options are not SOGC recommendations.

FETAL SEX

Depending upon the option you elect, the test results may include the sex of the pregnancy. If you do not wish to know the sex, please tell your health care provider not to disclose this information to you. Depending upon the test ordered, you may not be able to prevent learning the sex of your pregnancy. In rare instances, incorrect sex results can occur. In such cases, genetic evaluation may be recommended.

HOW SCREENING WORK

Cell-free DNA analysis is performed on a blood sample taken from a pregnant woman. A medical prescription is required. To confirm fetal viability and gestational age, EarlyReveal recommends that an ultrasound scan be performed prior to blood sampling. The sample of blood includes a combination of both your DNA and the DNA from the pregnancy. A technology called massively parallel sequencing is used to count the amount of DNA from each test chromosome and/or from specific regions of chromosomes. The laboratory then uses an analysis method to determine if each of the conditions you have elected to test for is likely to be present or absent.

SCREENING LIMITATIONS

A result of "no aneuploidy detected or low risk" does not guarantee a healthy pregnancy or a healthy baby, and does not eliminate the possibility of congenital anomalies, genetic problems or other problems being detected later in the pregnancy. Although rare, this type of screening carries the risk of false positives and false negatives.

There is a slight possibility that the results do not reflect the chromosomes of the fetus, but chromosomal changes in the placenta (placental mosaicism) or in you (maternal chromosomal abnormalities). Although these tests are not designed to assess your health, in some cases, information about your health may be revealed directly or indirectly.

In the case of a lost twin, the result may reflect a risk of chromosomal abnormality or the presence of a Y chromosome from the deceased fetus. In the case of twins, the status of each fetus cannot be determined. It is not yet known how long the residual DNA of the lost twin will circulate. We recommend that no irreversible clinical decision be taken on the basis of these results alone. Further tests may be required to confirm the results of your analysis (e.g. amniocentesis or chorionic villus sampling).

PREGNANCY RESULTS INFOMRATION

Collecting information about your pregnancy after testing is part of standard laboratory practice and is required in many circumstances. As such, EarlyReveal or its representative may contact your treating professional's team to obtain this information.

INCIDENTAL FINDINGS

The report will exclusively indicate the risk of chromosomal abnormalities targeted by the chosen screening, even if other chromosomal alterations may be present.

CONFIDENTIALITY

Your results will automatically be disclosed to your prescribing healthcare professional. However, they may be disclosed to other health care providers involved in your medical care, another person you designate in writing to act on your behalf, or otherwise in accordance with applicable laws.

USE OF INFORMATION AND REMAINING SAMPLES

In accordance with best practices and clinical laboratory standards, any remaining de-identified samples, genetic or other information obtained from your test may be used by EarlyReveal or others on its behalf for quality control, laboratory operations, research, laboratory test development and laboratory improvement. All such uses will be in compliance with applicable laws.

TIME LIMIT FOR OBTAINING RESULTS

Once the sample has been received at the laboratory, the average analysis time is 3 to 5 working days. EarlyReveal undertakes to use its best efforts to ensure that sample dispatch, analysis and results transmission are carried out as quickly as possible. EarlyReveal cannot be held responsible for any event causing additional delays.

REFUNDS FOR PRENATAL SCREENING TESTS

No refunds are possible once the analysis of the blood sample has begun. Otherwise, EarlyReveal will refund the value of the test less $155. However, if an ultrasound confirms that you were not at 10.0 weeks of amenorrhea at the time of your blood test, and you wish to repeat the test, an additional fee of 75% of the price of the chosen test will be charged.

FAILED ANALYSIS

The failure rate of EarlyReveal's NIPT tests is less than 1%. If the laboratory is unable to provide a result on the sample, a second sample will be taken free of charge and a new analysis will be started. If, after this second attempt, we are unable to issue a fetal DNA result, it will be classified as a failure, and will then be forwarded to your treating professional. A genetic consultation is recommended to discuss various evaluation options.