PLACE LABEL WITH ID INFORMATION HERE

EVITATEST COMPLETE

CLINIC: _____

PATIENT INFORMATION

Name (first): _____

Name (last): _____

Social security number: _____

Gestational age: _____

Postal Address: _____

Phone: _____

Email: _____

Consent to patient treatment

I confirm with my signature that I have received information from the clinic (indicated at the top of this consent form) about the treatment associated with EVITA TEST COMPLETE, including risks and complications, and that I have given my consent to the patient treatment in connection with EVITA TEST COMPLETE.

Find information about EVITA TEST COMPLETE and section on data protection on the back of this consent form.

Quality assurance and method optimisation

☐ By ticking the box on the left, I consent to Arcedi Biotech ApS, who has developed EVITA TEST COMPLETE, using the excess material from the blood sample, including any genetic and health information that may be derived from the blood sample and the test results for the laboratory's continued quality assurance and method optimisation, as well as for use in connection with the analysis of other EVITA TEST COMPLETE samples. Should new findings unexpectedly be made on my sample during method optimisation (rare incidental findings), I will be contacted in the event that a clinical geneticist assesses that it is clinically relevant information for me. I can withdraw my consent at any time by contacting Arcedi Biotech ApS by email kontakt@evitatest.dk.

I would also like to know the sex of the fetus: Yes ○ No ○

Signature: _____

EVITATEST COMPLETE

What is EVITA TEST COMPLETE?
EVITA TEST COMPLETE is a prenatal test that screens for genetic conditions of your unborn child. The test is non-invasive and is based on a blood sample taken from the pregnant woman between 10-14 weeks of gestation.
During pregnancy fetal cells from the placenta migrate into maternal blood circulation. By isolating these cells, the complete genome of the fetus can be accessed. EVITA TEST COMPLETE uses the fetal DNA to analyse genetic conditions that could impact your child's health or development. As EVITA TEST COMPLETE is based on fetal cells circulating in the maternal blood, the test is often referred to as cell-based non-invasive prenatal testing (cbNIPT).

Why choose EVITA TEST COMPLETE?
EVITA TEST COMPLETE is based on the latest technology within prenatal testing analysing fetal cells. EVITA TEST COMPLETE investigates for chromosomal changes (extra or missing parts of chromosomes) on all fetal chromosomes without inducing a risk of miscarriage.
Conditions such as trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome) along with other changes on the chromosomes that are assessed as clinically relevant by a clinical geneticist analysing the results, are revealed by EVITA TEST COMPLETE. The test can also reveal the sex of the fetus.
Alternatively, the invasive prenatal tests such as chorionic villus sampling (CVS) and amniocentesis provide definitive answers on all the chromosomes, but the methods require a tissue sample from the placenta or withdrawal of fluid from the uterus, respectively. Consequently, CVS and amniocentesis both involve a small risk of miscarriage.
EVITA TEST COMPLETE provides the missing link in prenatal testing that combines a, for the fetus, risk-free method with accurate screening of all chromosomes.
EVITA TEST COMPLETE is not suitable for twin pregnancies.

How to get EVITA TEST COMPLETE
1. The clinic will take 30 ml of blood sample from the pregnant woman
2. The blood sample is analysed
3. Within 12 business days, the pregnant woman will receive the genetic results by a phone call from the clinic.

Data protection
In connection with your purchase of EVITA TEST COMPLETE the clinic (as indicated on the frontpage of this consent form) will process your personal data, and the clinic is the data controller of this processing. The processing includes the information you provide on page 1 of this consent form as well as excess material from your blood sample, genetic information and any health information derived in connection with the chromosome analysis of your blood sample. In this regard, the clinic may also process information that is relevant to your EVITA TEST COMPLETE, e.g., information about previous abortions or diseases. The clinic processes your personal data in order to treat you in connection with EVITA TEST COMPLETE, and the processing of your personal data in this regard is based on the clinic's health tasks carried out in the public interest (Article 6(1)(e) and Article 9(2)(h) and (3) of the General Data Protection Regulation) and to be able to comply with the legal requirements to which the clinic is subject in accordance with the Danish Health Care Act and the Danish Executive Order on Medical Recordkeeping (Article 6(1)(c) and Article 9(2)(h) and (3) of the General Data Protection Regulation). The clinic will also process your social security number number in relation to the medical record (Section 11 (1) of the Danish Data Protection Act). The clinic stores the information regarding your EVITA TEST COMPLETE in your medical record, which, according to the Danish Executive Order on Medical Recordkeeping, must be stored for a minimum of 10 years from the last log in the medical record.

Arcedi Biotech ApS ('Arcedi'), who has developed EVITA TEST COMPLETE and the Region of Central Denmark (Region Midtjylland) help manage the analysis of your sample, based on a contractual instruction from the clinic. The Region of Central Denmark is obligated to keep a separate record of the analysis in accordance with the Danish Executive Order on Medical Recordkeeping. The Region of Central Denmark is also obliged to report your chromosome analysis to the Danish Cytogenetic Central Register (DCCR), which is a nationwide register where all chromosome analyses performed in Denmark are reported to. The Region of Central Denmark is independently responsible for these parts.

If you consent to it separately (by ticking of the box on the frontpage of this consent form), Arcedi may use the excess material from the blood sample, including any genetic and health information that may be derived from the blood sample, as well as test results for the laboratory's continued quality assurance and method optimisation, as well as use your analysis results in connection with the analysis of other EVITA TEST COMPLETE samples, including by compilation of analysis results (Article 6(1)(a) and Article 9(2)(a) of the General Data Protection Regulation). The transmission to Arcedi is also based on your consent according to both the data protection rules and the Danish Health Care Act. Arcedi stores your personal data for a minimum of 10 years. You can withdraw your consent at any time by contacting kontakt@evitatest.dk.
Arcedi may use data processors, acting solely on Arcedi's instructions, to process your personal data.

The clinic and/or Arcedi may use data processors established in countries outside the EU/EEA. In such case the transfer will be based on the EU Commission's standard contracts which you may obtain a copy of, and the clinic and/or Arcedi will have ensured that the transfer can take place without affecting the protection of your personal data.

Subject to certain statutory exceptions you always have the right to access the personal data we process and store about you. In addition, you have the right to object to our processing and the right to ask us to restrict the processing of your personal data. Furthermore, you have the right to request rectification and deletion of your personal data. If you wish to complain about the processing of your personal data, you can file a complaint to the Danish Data Protection Agency, Carl Jacobsens Vej 35, 2500 Valby, Denmark (e-mail dt@datatilsynet.dk).

You can contact the clinic as indicated at the frontpage of this consent form.
You can contact Arcedi on kontakt@evitatest.dk or +45 9396 0000.
Arcedi is located at Tabletvej 1, 7100 Vejle, Denmark.

V03-08-2023

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