1 CONSENT FORM

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PUB-1310-V04-04-2025

CLINIC INFORMATION

Clinic name: _____

PLACE LABEL WITH ID INFORMATION HERE

PATIENT INFORMATION

First name: _____

Last name: _____

Social security number: _____

Date of birth (DD/MM/YYYY): _____ Gestational age: _____

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 fetal genetic screening in connection with EVITA TEST COMPLETE. Below you can find information about EVITA TEST COMPLETE and the data protection policy.

Data protection legal consent

By ticking the box(es), I consent to ARCEDI Biotech ApS, who has developed EVITA TEST COMPLETE, that it can:

- ☐ use the analysis results, including the genetic information, to measure the performance of EVITA TEST COMPLETE in connection with the analysis of other EVITA TEST COMPLETE samples.
- ☐ use excess of the 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 method optimization.
- ☐ collect my final results from the clinic for the laboratory's continued quality assurance (and that the clinic may disclose my final result for this purpose).

I can withdraw my consent at any time by contacting ARCEDI Biotech ApS by email: info@evitatest.com.
Should new findings be made unexpectedly on my sample during method optimization (incidental findings), I will be contacted in the event a clinical geneticist assesses that it is clinically relevant information for me.

I would also like to know the gender of the fetus: Yes ☐ No ☐

Your signature: _____

EVITA TEST COMPLETE
EVITA TEST COMPLETE is a prenatal screening test. It is the only risk-free non-invasive prenatal test (NIPT), that analyzes all fetal chromosomes in intact fetal cells for aneu-ploidies as well as deletions down to 2 Mb and duplications down to 5 Mb. Furthermore, pathogenic deletions and duplications smaller than these in regions linked with known syndromes are reported. These include e.g. Prader-Willi syndrome, Angelman syndrome, William's syndrome, 1p36 microdeletion syndrome, Cri-du-chat syndrome, Wolf-Hirschhorn syndrome, 22q11 deletion syndrome, and Smith-Magenis syndrome. The test can be taken in gestational week 10+0 to 14+6, and most often the answers will be reported within 12 workdays.

Limitations
EVITA TEST COMPLETE is a screening test and is not diagnostic. There is a small risk of false positive and false negative results. Any medical decisions regarding the test results should only be taken after a discussion with a specialist healthcare professional. EVITA TEST COMPLETE cannot detect:
Polyploidy, balanced translocations, monogenic syndromes, and uniparental disomy. EVITA TEST COMPLETE has a lower sensitivity for mosaicism. Fetal cells are rare and in approx. 6 % of all pregnancies, not enough fetal cells can be found to carry out the genetic examination. This has no known correlation with the pregnancy outcome. In these cases, a new blood sample is offered (within week 10+0 to 14+6). The percentage of samples, where not enough fetal cells can be found, then decreases to approx. 2 %.

Data protection
In connection with the analysis of your EVITA TEST COMPLETE sample, ARCEDI will process your personal data as a data controller. 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, ARCEDI also process information that is relevant to your EVITA TEST COMPLETE, e.g., information about previous abortions or diseases if we receive such information from the clinic from which you bought the EVITA TEST COMPLETE. ARCEDI 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 ARCEDI's health tasks carried out in the public interest (Article 6(1)(e) of the General Data Protection Regulation ("GDPR") and Section 7 (3) of the Danish Data Protection Act ("DPA"), cf. Article 9(2)(h) and (3) of the GDPR, cf. Section 41(1) of the Danish Health Care Act ("HCA")) and to be able to comply with the legal requirements to which ARCEDI is subject in accordance with the HCA and the Danish Executive Order on Medical Recordkeeping (Article 6(1)(c) of the GDPR and Section 7 (3) of the DPA, cf. Article 9(2)(h) and (3) of the GDPR and Section 41(1) of the HCA). ARCEDI does also carry out quality assurance to ensure that EVITA TEST COMPLETE works properly and is accurate (Section 10 (1) of the DPA, cf. Section 42d(2) of the HCA). ARCEDI will also process your social security number in relation to the medical record (Section 11 (1) of the DPA). ARCEDI 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. Information which is not included in your medical record is deleted after a maximum of 6 years.
The Region of Central Denmark (Region Midtjylland) may help manage the analysis of your sample, based on a contractual instruction from ARCEDI. The Region of Central Denmark is required by law to keep independent medical records in accordance with the Danish Executive Order on Medical Recordkeeping, which the Region of Central Denmark is an independent data controller for. In addition to this, the Region of Central Denmark is required to report Danish citizens' chromosome analysis to Dansk Cytogenetisk Centralregister (DCCR) which is a national register of all chromosome analyses in Denmark.
Furthermore, ARCEDI may process your personal data in connection to concrete research projects approved by The Danish Research Health Ethics Committee (cf. Article 6(1)(f) of the GDPR and Section 10 of the DPA, cf. Section 46(1) of the HCA). If you consent to it separately (by ticking of the box on the frontpage of this consent form), ARCEDI may i) use your analysis results in connection with the analysis of other EVITA TEST COMPLETE samples, including by compilation of analysis results, ii) use the excess material from the blood sample, including any genetic and health information that may be derived from the blood sample and test results for the laboratory's continued method optimization, and iii) receive your final results from the clinic for the purpose of ARCEDI's quality assurance (cf. Article 6(1)(a) and Article 9(2)(a) of the GDPR). ARCEDI stores your personal data for a maximum of 11 years. You can withdraw your consent at any time by contacting info@evitatest.com.
ARCEDI may use data processors, such as providers of IT systems, acting solely on ARCEDI's instructions, to process your personal data. Your personal data will not be transferred to countries outside EU/EEA without an adequate level of protection.
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 as well as 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 (email dt@datatilsynet.dk). You can contact the clinic as indicated at the frontpage of this consent form. You can contact ARCEDI on info@evitatest.com.dk or +45 9396 0000 (09.00 AM to 11.30 AM). ARCEDI is located at Tabletvej 1, 7100 Vejle, Denmark.