AANVRAAGFORMULIER Niet-Invasieve Prenatale Test

BELNIPT whole genome

Whole genome NIPT voor screening van trisomie 13, 18 en 21 **vanaf de 12de zwangerschapsweek**.
Uitgevoerd met VeriSeq™ NIPT Solution (Illumina, USA) in samenwerking met het BELNIPT consortium

Het is de verantwoordelijkheid van de aanvrager om de aanvraag volledig en correct in te vullen, te ondertekenen en de klinische gegevens kenbaar te maken.

PATIËNTGEGEVENS *(volledig invullen of vignet kleven a.u.b).*	**AANVRAGER**
Naam: ……	Dr. ……
Voornaam: ……	RIZIV nr.: ……
Adres: …… Nr. ……	Aanvraagdatum (DD-MM-JJJJ):
Postnr.: …… Gemeente: ……	☐☐-☐☐-☐☐☐☐
Geboortedatum: ☐☐-☐☐-☐☐☐☐	Handtekening: ……
Mutualiteitsgegevens: ……	☐ Rapportkopie aan huisarts
☐ Gehospitaliseerde patiënt	
Rijksregisternummer: ……	

Geïnformeerde toestemming: VERPLICHT IN TE VULLEN OP ACHTERZIJDE

NIPT – screening trisomie 13, 18 en 21 (5769)

Gegevens moeder:

Gewicht vóór zwangerschap: …… kg Lengte: …… cm

Gekende maternale aneuploïdie of familiale anamnese genetische aandoeningen: ☐ Ja ☐ Nee

Specifieer: ……

Belangrijke preanalytische gegevens of contra-indicaties:

☐ Heparine/LMWH therapie ☐ Bloedtransfusie < 3 maanden ☐ Stamceltransplantatie ☐ Orgaantransplantatie

☐ Maligniteit bij moeder ☐ Auto-immune ziekte (SLE, RA, thyroïditis,…)? Zo ja, specifieer:……

Zwangerschapsgegevens:

Zwangerschapsduur bij NIPT aanvraag: …… w ……d (**minimaal 12 weken**)

Verwachte geboortedatum: …… /…… /……

☐ Eiceldonatie

☐ Meerlingzwangerschap: → ☐ DCDA (dichoriaal-diamniotisch) ☐ MCDA (monochoriaal-diamniotisch) ☐ MCMA (monochoriaal-monoamniotisch)

Aantal foetussen: ……

☐ Indien aanvankelijk meerling zwangerschap, specifieer: ……

Risicofactoren:

☐ Echografische afwijking? Zo ja, specifieer:……

☐ Precedent trisomie? Zo ja, specifieer: ……

Voorbehouden voor de bloedafname:

Het bloedstaal van de moeder (**1 STRECK buis**) dient onmiddellijk na afname te worden gemengd d.m.v. zachte, 10-voudige inversiebeweging, op kamertemperatuur te worden bewaard en binnen de 24 uur in het uitvoerend laboratorium te worden afgeleverd.

Datum afname: …… /…… /…… **Tijdstip afname**: …… u ……min

NIPT: INFORMED CONSENT

1. I was informed about the possibilities and limitations of NIPT as described in the information brochure provided by AZ Delta. I had the opportunity to discuss this information with my gynecologist and ask additional questions.
2. I understand that a NIPT test costs 260 euro and is near-completely reimbursed if I am covered by the Belgian health care system (RIZIV/INAMI). I only pay a personal contribution of 8,68 euro unless I meet the criteria for extensive support. NIPT done before pregnancy week 12 is NOT reimbursed and the full sum will be charged.
3. I understand that NIPT is a screening test for trisomy 21, 18 and 13 but not a diagnostic test. My VeriSeq™ NIPT has a sensitivity of more than 99% for the detection of trisomy 21. This means that the test correctly identifies at least 99 out of 100 pregnancies affected by Down syndrome. For trisomy 18 and 13, sensitivities are 90% and 100% respectively. This implies that a normal NIPT result can never completely rule out trisomy 21, 18 or 13, but that the odds of a so called 'false negative' result are very limited. Vice versa, an abnormal NIPT result does not always mean that the baby has a chromosomal defect. Therefore, if I receive an abnormal NIPT result, I will be proposed to undergo follow-up diagnostic testing through amniotic puncture.
4. NIPT technology was developed to screen for large DNA defects such as the extra copy or loss of an entire chromosome. Most common hereditary diseases (e.g. cystic fibrosis or hemophilia) are not caused by such large defects, but rather by very small errors in the genetic code. I understand that NIPT cannot detect such small errors. I understand that if such diseases run in my family, I should notify my gynecologist for alternative testing and prenatal genetic counseling.
5. I understand that whole-genome NIPT such as VeriSeq™ measures fragments of all chromosomes. I understand that rarely (approximately 2 in 1000) NIPT detects abnormalities in other chromosomes than 13/18/21/X/Y in the mother or the fetus. I understand that if such abnormalities are considered medically relevant, I will be notified for follow-up testing through amniotic puncture.
6. I understand that VeriSeq™ NIPT is also certified (CE-IVD) for the screening of abnormalities of the number of X- and Y-chromosomes in the fetus. In those abnormalities, the baby has an extra copy of X-and Y-chromosome, or has lost one X-chromosome. The most important abnormalities are female babies with **Turner syndrome** and boys with **Klinefelter syndrome**. The actual sensitivity of VeriSeq™ NIPT to screen these syndromes is not known. But if the test suggest a baby with Turner or Klinefelter syndrome, this is typically confirmed in 80% to 100% of cases in subsequent amniotic puncture. Abnormalities of the sex chromosomes are always measured by VeriSeq™ NIPT, but **by default they are NOT reported to you. Only if you explicitly chose to be informed about X or Y abnormalities by indicating "yes" in the field below:**

☐ **Yes, if VeriSeq™ NIPT indicates an abnormality of the fetal sex (X/Y) chromosomes, I wish to be informed**

7. I understand that VeriSeq™ can correctly determine the genetic sex of my fetus in at least 97% of cases. Echographic confirmation is however always required. The sex of the fetus is always measured, but **by default it is NOT reported to you on the test report unless you explicitly chose to be informed by indicating "yes" in the field below:**

☐ **Yes, I wish to be informed about the sex of my fetus (5770)**

8. I understand that in rare cases (<2%) the NIPT test is inconclusive due to a low amount of fetal DNA in the circulation (low fetal fraction) or shows some kind of technical interference. In that case, I will be contacted by the laboratory for a new blood draw. The NIPT test will then be repeated once at no extra cost.
9. I give permission to the laboratory to archive my DNA data and residual blood sample indeterminately, and use both for research, development and educational purposes with strict anonymization and protection of my privacy conform the EU GDPR directive. The outcome of my NIPT test will be archived in a database for quality control monitoring. I understand that I can be contacted by a medical doctor of the laboratory if additional outcome data of my baby after birth are needed for improvement of NIPT. I have the right to request deletion of my DNA data without any consequence.
10. I understand that I will receive my NIPT test result via e-mail under the form of a password encrypted pdf, directed to the **email address provided below**. Most results are available within 1 week after blood sampling.

Signature mother

Surname, given name: …… Date: …….. /…….. /……..

Mobile:……

Email:…….. PLEASE USE CAPITAL FONT FOR LEGIBILITY

Signature: