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Request form for screening of fetal aneuploidy (NIPT)

Administrative information (fill out or adhere mutual insurance label)

SURNAME, FIRST NAME

Patient _____ Your reference: _____

Date of birth : _____

Address : _____

Healthcare Provider: _____

Clinical information about pregnancy (please fill out)

Duration of pregnancy : _____ weeks _____ days

Type of pregnancy : ☐ Singleton ☐ Twin ☐ Triplets or more

Suspicion of vanishing twin? ☐ Yes ☐ No

Egg cell donation? ☐ Yes ☐ No If yes, age of donor ? _____ years

Informed consent of the pregnant woman (read overleaf of this form)

- I am well informed about the possibilities and restrictions of this NIPT, as described on the overleaf of this page. I have had sufficient opportunity to ask my physician additional information about the test.
- I understand that this test is intended to detect trisomy 13,18 and 21 of the fetal chromosomes. Optional test expansion to all chromosomes can be done after my explicit consent.
- I understand that this test is highly accurate, nevertheless not 100%. In case of a normal result, there is still a small chance that aneuploidy of the investigated chromosomes can occur.
- In case I wish to know the sex of the fetus, there is a small chance an abnormal result can be found. Interpretation of these results is not always fully conclusive.
- NIPT is a screening test, each deviant result needs to be confirmed by an invasive prenatal test.
- I understand that in exceptional cases (insufficient quality/quantity of fetal DNA, damaged blood sample or abnormal test procedure) no result can be generated. In such event, the test can be repeated on a new blood sample.
- I agree with execution of this test for prenatal detection of fetal trisomy 13, 18 or 21 (and optional other chromosomes).

- I wish to know the sex of the unborn child: ☐ Yes ☐ No
- I wish to expand the test to all chromosomes: ☐ Yes ☐ No

Patient Signature :

Date : ___ ___ _____

Blood draw : 1 completely filled cell-free DNA tube.

Requesting physician
(Signature)

Prescription date : ___ ___ _____
Date of draw: ___ ___ _____ Time : ___ ___

BARCODE

Collector : _____
☐ Non-conform
☐ No signature
☐ Streck Tube
☐ Roche Tube
☐ Other : _____

Information about NIPT (Non-Invasive Prenatal Testing) executed at Sonic Healthcare Belgium – AML (Algemeen Medisch Laboratorium)

Trisomy 21, 18 and 13 are the three most important anomalies of the carriers (chromosomes) of the genetic material (DNA). These anomalies are characterized by the presence of an entire strand of extra genetic material (chromosome 21, 18 or 13). People with one of these defects show very characteristic facial features, mental disabilities and often multiple organ disorders. There are at this moment no curative treatments for these three diseases.

The **N**on-**I**nvasive **P**renatal **T**est (NIPT) estimates the risk of an unborn child (fetus) to have extra chromosome in the foetus. Detection of fetal DNA in the mother's blood is made possible by next-generation sequencing technology (VeriSeq NIPT Solution). The method is not invasive and only requires a blood draw by the pregnant woman, hence does not increase the risk for miscarriage or infection of de uterus.

International scientific guidelines recommend testing for presence of trisomy 21, 18 or 13 at the fetus. Because the NIPT at Algemeen Medisch Laboratorium (AML) is based on a whole genome approach, all chromosomes can be evaluated, and other rare autosomal trisomy's can be detected. Not only anomalies of full chromosomes can naturally occur and can be detected, but partial, sub-chromosomal alterations can be found. The clinical impact of such variants is still incompletely understood, and testing of all chromosomes is still topic of intensive ethical debate. Therefore, explicit consent of the mother is requested to additionally report these findings. The NIPT test is highly accurate, nevertheless not 100%. In case of a normal result, there is still a small chance that aneuploidy of chromosomes can occur.

This test allows to determine the sex of the fetus. This is also optional and will only be reported after consent of the pregnant woman. There is a very small chance that the result of the genetic gender is abnormal. (e.g. Turner syndrome or Klinefelter syndrome). Sometimes effects of the alterations for the unborn child are unclear.

There is a small chance (<0,3% of the cases) that no result could be generated. Causal factors include insufficient amount of fetal DNA or low DNA quality, damaged blood sample, or unusual course of the test. In this case a new test can be execute on a new blood sample, free of charge.

The presence of ''unexptected'' DNA due to blood transfusions, transplantation or stem-cell therapy in the blood of the pregnant woman could lead to an incorrect result. Known or unknown congenital or acquired (e.g. tumors) genetic alterations from the pregnant woman could influence test interpretation.

<u>Although this is a very accurate test, it is compulsory to confirm every positive result by an invasive prenatal test, preferably by amniocentesis.</u>

Pursuant to best practices and clinical laboratory standards, leftover de-identified specimens may be used for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable laws. *I agree* ☐ *do not agree* ☐ (if left blank, we assume your approval).