AMPATH LABORATORIES

PR0520005200431

DRS DU BUISSON, KRAMER, SWART, BOUWER INC.

REFERRING DOCTOR	
COPY DOCTOR	

PLACE BARCODE HERE

CLINICAL DIAGNOSIS/ MEDICATION		MEDICAL AID	PLAN
		MEDICAL AID NO.	DEP. CODE
ICD-10 CODES	Z36.0	MEDICAL AID AUTH.	STAT ROUTINE

PATIENT DETAILS

ID NUMBER
SURNAME TITLE
INITIALS & FIRST NAME AGE
DATE OF BIRTH D D M M Y Y Y Y SEX ASSIGNED AT BIRTH M F
HOSPITAL/ FOLIO NO.
CELL (H)
(W)
EMAIL

PERSON RESPONSIBLE FOR ACCOUNT (GUARANTOR)

GUARANTOR ID NUMBER
SURNAME
INITIALS & FIRST NAME TITLE
POSTAL ADDRESS
POSTAL CODE
CELL (H)
(W)
EMAIL

PATIENT/GUARDIAN SIGNATURES:
I confirm acceptance of the informed consent available at ampath.co.za. I verify that all personal information is correct. Y N

GUARANTOR'S SIGNATURE:
I consent to the requested tests and guarantee payment thereof. I consent that ICD10 codes may be provided to my medical aid as per statutory requirements on my account. Y N

PHLEBOTOMY SITE
COLL. DATE D D M M Y Y Y Y
COLL. TIME COLL. BY
FASTING Y N PREGNANT Y N
THYROID MEDICATION Y N ON ANTI COAGULANT Y N
REC. DATE D D M M Y Y Y Y
REC. TIME REC. BY

HOSPITAL PATIENT Y N
NO OF TUBES DRAWN S01 S02 E01 E02 HEP CIT FLU MICRO / OTHER
TEST COUNT

Non-invasive Prenatal Testing (NIPT)

Pregnancy information

Gestational age: _____ weeks _____ days
Patient weight: _____ kg
Patient height: _____ m

Test indications

- ☐ Increased risk serum screen
- ☐ Advanced maternal age
- ☐ Ultrasound abnormality
- ☐ Previous pregnancy with chromosome anomalies
- ☐ Patient concern/anxiety

Number of foetuses

- ☐ Singleton
- ☐ Twin
- ☐ Vanishing twin

Risk stratification

- ☐ High (<1:300)
- ☐ Intermediate (1:300-1:1000)
- ☐ Low (>1:1000)

Testing options

	Foetal sex/gender	Mnemonic
☐ Chromosomes (Trisomy) 21, 18, 13	Y N	NIPT1
☐ Chromosomes (Trisomy) 21, 18, 13 AND sex chromosome aneuploidies	Y N	NIPT2
☐ All chromosomes* (includes segmental deletions and duplications >7Mb. Does NOT include microdeletions)	Y N	NIPT3

*Pre-test genetic counselling is STRONGLY recommended for this option. Microdeletions can be performed on special request only.

Contact nipt@ampath.co.za.

PATIENT CONSENT
My signature below indicates acceptance of the patient consent on the reverse of this form.

_____ Patient signature _____ Date

Additional consent:

I would like to be informed should a sex chromosome abnormality be inadvertently detected during the NIPT1 test: Y N

_____ Patient signature _____ Date

CLINICIAN ATTESTATION
I hereby certify and undertake that the patient has been informed that the NIPT will only test for the disorders requested on this form and has been thoroughly counselled about the test, including the benefits, risks and limitations of NIPT. The patient has received all the advice necessary to provide their informed consent.

_____ Clinician signature _____ Date

Item Code: 001795

Updated 23 June 2025

OUR STANDARD PRICE LIST IS AVAILABLE AT ANY CARE CENTRE

SI DIGITAL - OCTOBER 2024

Non-Invasive Prenatal Test (NIPT) Patient Informed Consent

INTRODUCTION:
This form describes the benefits, risks, and limitations of the NIPT available through Drs Du Buisson , Kramer, Swart, Bouwer Incorporated hereinafter referred to as "Ampath Laboratories". Pre-test counselling is essential and should be provided by an experienced healthcare provider prior to testing. The NIPT1/2/3 options offered are performed at a local referral laboratory (Next Genetics, referred to below as the "Performing Laboratory"), using Illumina Next Generation Sequencing (NGS) technology. Please read this form carefully and discuss any questions you may have with your healthcare provider before making your decision about testing. Ampath also provides genetic counselling services on request.

PURPOSE AND TEST OPTIONS:
The purpose of the NIPT is to screen your pregnancy for certain chromosomal anomalies, also known as "aneuploidies". The tests can provide information about extra copies (trisomy) of certain chromosomes. Trisomy 21, trisomy 18 and trisomy 13 are three of the most commonly occurring trisomies seen in babies at birth. NIPT can be performed as early as 10 weeks 0 days gestational age. Consult your healthcare provider if you would like more information about this screening test, including risks, limitations, performance data, error rates, descriptions of the conditions being screened, and what these results may mean to your pregnancy. The tests available can provide information about the following chromosomes:

NIPT1
• Trisomy 21, 18, and 13

NIPT2
• Trisomy 21, 18, and 13 and sex chromosome aneuploidies (abnormalities of X/Y)

NIPT3
• Screens for aneuploidies (extra or missing copies) in all chromosomes as well as deletions or duplications of chromosome material 7Mb or larger (called segmental aneuploidies).
• This option is not available in twin pregnancies

Reporting of the fetal sex is optional with the above options.

HOW THIS TEST WORKS:
This test screens for specific chromosomal anomalies (aneuploidies) by looking at the cell-free placental DNA (genetic material) in your blood. During pregnancy DNA from the placenta circulates in the mother's bloodstream. The sample of blood includes a combination of maternal DNA and the DNA from the placenta. Fetal fraction is the term given to the proportion of cell-free DNA belonging to the placenta found in the mother's blood. A technology called massively parallel sequencing or next generation sequencing is used to count the amount of DNA from each chromosome being tested and/or from specific regions of chromosomes. The laboratory then uses an analysis method to determine if chromosomal aneuploidies are likely to be present or absent.

SEX OF FOETUS:
Depending upon the option you and your healthcare provider elect, the test results may include the sex of the foetus. If you do not wish to know the sex, please ensure that this is indicated on the request form. In rare instances, incorrect sex results can occur for example in the situation of a vanishing twin where residual DNA from the vanishing twin may persist.

LIMITATIONS OF THE TEST:
These tests are screening tests and not diagnostic. They do not replace the accuracy and precision of prenatal diagnosis with chorionic villus sampling or amniocentesis. A patient with a positive test result should be referred for genetic counselling and offered invasive prenatal diagnosis for confirmation of test results.

- A 'no anomaly detected' result does not guarantee a healthy pregnancy or baby and does not eliminate the possibility that your pregnancy may have birth defects, genetic conditions or other conditions, such as an open neural tube defect or autism. These tests may not accurately identify fetal triploidy (three copies of every chromosome instead of two) or balanced chromosomal rearrangements.
- There is a possibility that the test results might not reflect the chromosomes of the foetus but may reflect chromosomal changes occurring in the placenta only (confined placental mosaicism, CPM) or of you (maternal chromosomal abnormalities).
- In addition, mosaicism may occur in which there is a combination of genetically normal and abnormal cells in the placenta and/or foetus that may occur at different percentages relative to each other and may influence the results of the test.
- These tests, like many tests, have limitations, including false negative and false positive results. This means that the chromosomal abnormality being tested for may be present even if you receive a negative result (this is called a 'false negative'), or that you may receive a positive result for the chromosomal abnormality being tested for, even though the abnormality is not actually present (this is called a 'false positive'). You confirm that you are aware of the limitations with these tests and that a 'false positive' or 'false negative' result may occur.
- In the case of a vanishing twin, the test result may reflect the DNA of the vanishing twin, leading to a higher probability of false positive or false negative results.
- In some cases, we may not be able to obtain a result, the causes of which may include among other, technical limitations or insufficient fetal fraction.
- Testing for whole chromosome aneuploidies (including sex chromosomes) and for segmental chromosome aneuploidies could lead to the potential discovery of both fetal and maternal genomic anomalies that could have major, minor, or no, clinical significance. Evaluating the significance of a positive or inconclusive result may involve both invasive testing and additional studies on the mother. Such investigations may lead to a diagnosis of maternal chromosome or segmental aneuploidies, which on occasion may be associated with benign or malignant maternal neoplasms (cancer).
- Some rare chromosomal aneuploidies may only occur in mosaic form. Clinical consequences depend on the chromosome involved and cannot be predicted prenatally.
- In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations, also known as "secondary findings" may become evident. Our policy is to NOT REPORT on any secondary findings that may be noted in the course of analysing the test data, but the information may be discussed with your healthcare provider.

You must consult your healthcare provider for more information about your results and what they may mean for your pregnancy, what options you will have for further testing, and whether additional testing is recommended for you based on your clinical history. No irreversible clinical decisions should be made based on these screening results alone. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis is necessary. Ampath Genetics is able to offer you genetic counselling services on request.

TEST PROCEDURE:
A tube of your blood (single 10ml tube) will be drawn by Ampath Laboratories and referred to the performing laboratory which will then analyse the sample. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection. The test is performed after 10 weeks, 0 days of pregnancy. After analysis the test results will be reported returned to your healthcare provider, who will discuss them with you as part of the ongoing management of your pregnancy. In the event of additional samples being required, Ampath Laboratories shall arrange for this to be done. Additional samples may be required in the event of a Quality Control failure or when sample acceptance criteria is not met upon sample receipt. Sample acceptance criteria includes: At least 10 weeks gestational age, sample volume of >7ml, sample in correct non- expired tube, sample is not visibly compromised, sample clearly labelled, transit time does not exceed 5 days at room temperature.

IMPORTANT POINTS ABOUT THE TESTING AND REPORTING PROCESS:

1. Your test results are confidential.
2. Your results will only be disclosed to your ordering healthcare provider(s) as listed on your test requisition form, which you consent to.
3. Only authorised and requested tests as per your test requisition form will be performed on your identifiable blood sample.
4. Your sample will be kept for a minimum 24 months. This is in line with international best practice.
5. Ampath Laboratories may from time to time collect information on your pregnancy after testing. As such Ampath Laboratories may contact your healthcare provider to obtain this information, which you consent to.
6. Pursuant to best practices and clinical laboratory standards, leftover de-identified (anonymous) specimens as well as de-identified (anonymous) genetic and other information learned from your testing, may be used by Ampath Laboratories for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement, which you consent to. All such uses will be conducted in compliance with applicable laws.
7. Ampath Laboratories may also use your leftover specimen and health information, including genetic information, in an anonymised or de-identified form, for research purposes, which will be carried out in compliance with applicable law. Such uses may result in the development of commercial products and services. You consent to these uses and agree that you will not receive notice of any specific uses and you will not receive any compensation for these uses nor derive any benefit from any commercial products or services which may be developed arising from these uses.
8. You agree and accept that the maximum aggregate of all and any amounts which Ampath Laboratories may be liable for in respect of any claims arising from the testing services performed in terms of your test requisition form (whether to you or any third party), will be limited to the amount paid by you to Ampath Laboratories for such testing services.

COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA):

- You consent that your Personal and Special Personal Information as defined in the Protection of Personal Information 4 of 2013 ("POPIA") be transferred the Performing Laboratory who will conduct the tests and who may in terms of section 72 transfer your information abroad for purposes to generate the test and or to assist Ampath and or the Performing Laboratory to finalise the test., If your aforesaid information is transferred abroad, Ampath Laboratories and Performing Laboratory as Ampath Laboratories' Processor will ensure that it is transferred subject to laws not less stringent than POPIA and that the Recipient shall use it only for purposes to assist with the test which Recipient shall have proper IT and corporate procedures in place to safeguard and protect the integrity of such information.
- You understand that Ampath Laboratories takes the privacy of its patients very seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of your private patient information (Personal Information). Your test results and data will be stored in Ampath Laboratories' database and will be processed in accordance with the Protection of Personal Information Act 4 of 2013 and that biological material obtained from me will be used in terms of the relevant Regulations of the National Health Act 61 of 2003.
- You acknowledge that your Personal Information may be disclosed to Ampath Laboratories, or to Ampath Laboratories' affiliates, sub-contractors and vendors, solely for the purposes of providing the testing services.
- You acknowledge that your Personal Information may be disclosed by Ampath Laboratories in response to a specific request by a law enforcement agency, subpoena, court order, or as required by law.
- You confirm that the Personal Information supplied by you is true and correct and that you are responsible for updating your information to ensure that it remains correct.
- You acknowledge that your Personal Information will be retained by the Performing Laboratory for the required retention periods applicable to the medical and healthcare industry.

In providing the testing services to you, your Personal Information may be transferred outside of South Africa, which you agree and consent to. Ampath Laboratories has ensured that all information transferred is done in an encrypted format.

FOR ANY ADDITIONAL INFORMATION, CONTACT AMPATH GENETICS AT 012 678 0645 OR EMAIL NIPT@AMPATH.CO.ZA