MEDICLINIC PRECISE

in partnership QLAB

natera™ | Panorama™ Next-generation NIPT

Natera LIMS ID: 24019

NON-INVASIVE PRENATAL TESTING REQUEST FORM

MEDICLINIC BARCODE

NATERA BARCODE

REFERRING CLINICIAN INFORMATION

Referring clinician:

Tel: –

Email:

Practice no.:

HPCSA no.:

PATIENT INFORMATION

ID no.:

Name:

Surname:

Date of birth: D D M M Y Y Y Y

Cell phone: –

Email:

Physical address:

Suburb: Postcode:

City:

PERSON RESPONSIBLE FOR THE ACCOUNT

ID no.:

Name:

Surname:

Cell phone: –

Email:

Physical address:

Suburb: Postcode:

City:

Medical aid:

Medical plan:

Medical aid no.: Cash: *(Tick if yes)*

I confirm that the information is correct and consent to the test analysis. I confirm that my pathology results and accounts from Mediclinic Precise may be sent to my nominated email address, my medical aid administrators and the referring doctor. I acknowledge that by submitting my claim to my medical scheme for reimbursement, my medical scheme will become aware of my diagnosis. I undertake to pay outstanding monies not covered by the medical aid.

Name: Date: D D M M Y Y Y Y

Signature:

SCREENING TEST OPTIONS

ICD CODE: Z13.7

- **PANORAMA PRENATAL PANEL**
  Chromosomes 13, 18, 21, X and Y; Triploidy
- **PANORAMA PRENATAL PANEL + 22q11.2 DELETION**
  Chromosomes 13, 18, 21, X and Y; Triploidy, 22q11.2 deletion
- **PANORAMA EXTENDED PANEL**
  Chromosomes 13, 18, 21, X and Y; Triploidy, 22q11.2 deletion PLUS four microdeletions

INCLUDE FETAL SEX ON REPORT? Y N

COLLECTION INFORMATION

Collection date: D D M M Y Y Y Y

Collection time: H H : M M

Collection place:

Person collecting:

Signature:

PREGNANCY-RELATED INFORMATION

We do not accept vanished twin, multiple gestation with more than two fetuses, or twins conceived using a surrogate or egg donor. Extended panel is not available for twins or egg donors.

IVF-conceived pregnancy? Y N

Age of mother at egg retrieval:

Did the patient use an egg donor or surrogate? Y N

Is this a multiple gestation pregnancy? Y N

If it is an ongoing twin pregnancy

- Monochorionic
- Dichorionic
- Do not know

PATIENT MUST BE AT LEAST 9 WEEKS 0 DAYS GESTATIONAL AGE

GESTATIONAL AGE

Weeks Days

IF MOTHER WEIGHS > 80kg, DEFER TESTING UNTIL 12 WEEKS 0 DAYS GESTATIONAL AGE

MATERNAL WEIGHT (kg)

MATERNAL HEIGHT (cm)

EXPECTED DUE DATE

D D M M Y Y Y Y

SPECIMEN INFORMATION

Sample type: 2x Streck tubes* containing 10ml maternal peripheral blood each – no other sample type will be accepted. **Cell-free DNA BCT by STRECK*

SAMPLES NEED TO BE KEPT AT ROOM TEMPERATURE AND SHOULD REACH THE LABORATORY WITHIN TWO DAYS OF COLLECTION FOR OPTIMAL SAMPLE VIABILITY

MEDICLINIC PRECISE'S OFFICES: 0861 444 558, nipt.precise@mediclinic.co.za, www.mediclinic.co.za/precise, 108 Albert Road, Woodstock 7925, Cape Town, South Africa

Informed Consent for Genetic Testing – Clinical Tests

NON-INVASIVE PRENATAL TESTING

PURPOSE OF THE TEST(S)

The Non-invasive Prenatal Test is used to:

1. Screen the fetus for chromosome abnormalities according to the selected panel (see reverse)
2. Report the fetal sex (should you wish to know)

The test is performed on a blood sample from the mother, who should be at least 9 weeks pregnant. The mother's blood contains cell-free DNA from both her and the fetal placenta. This fetal placenta DNA is identical to the DNA found in the fetus in approximately 98% of pregnancies.

If you are already aware of a specific gene variant (or variants) that cause(s) a genetic disorder in your family, please provide the information to your healthcare provider, who will share it with us.

For more information about each genetic condition screened for in each panel option, please visit the Mediclinic Precise website

TEST RESULTS

Your test results will be sent to the healthcare provider who ordered the test. The results will indicate whether your fetus has a **'low'** or **'high' likelihood or risk** of one the chromosome abnormalities tested but cannot confirm that the fetus has that abnormality. Additional diagnostic testing, such as chorionic villus sampling, amniocentesis or testing the baby after delivery, is recommended for confirmation before an irreversible decision is made. Your healthcare provider will discuss the follow-up tests with you, which may include a referral to a specialist and support from a genetic counsellor.

There is a chance that the sample submitted may not return a result or will only return a partial result. A repeat sample will be requested and another blood draw arranged. However, please note that a repeat sample does not always return or necessarily guarantee a result. This may indicate an unchanged or increased risk for the fetus to have the chromosome abnormality. Your healthcare provider will discuss options with you including a comprehensive ultrasound evaluation or other diagnostic testing.

DECISIONS ABOUT YOUR PREGNANCY SHOULD NEVER BE MADE BASED ON THESE SCREENING RESULTS ALONE, AS THEY NEITHER CONFIRM NOR RULE OUT THE PRESENCE OF A CHROMOSOME ABNORMALITY IN THE FETUS.

GENETIC COUNSELLING

If you have remaining questions about this genetic test after talking with your healthcare provider, we recommend that you speak with a genetic counsellor, who can give you more information about your testing options. We can facilitate a genetic counsellor to assist with this.

TEST LIMITATIONS AND RISKS OF GENETIC TESTING

1. Although this screening test will detect the specific chromosomal conditions screened for in the majority of pregnancies, it cannot detect 100% of pregnancies with these abnormalities.
2. The results of the test do not eliminate the possibility of other abnormalities within the tested chromosomes, other chromosomes, other genetic disorders, birth defects or other complications in your fetus.
3. The test is called Panorama and was developed by Natera, Inc., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test is not cleared by the US Food and Drug Administration (FDA).
4. Inaccurate results or a failure to obtain test results is a rare occurrence and may be due to one or more of the following: courier or shipping delay, the mislabelling of samples, laboratory failure or error, sample contamination or degradation, too little DNA from the fetus present in the maternal blood, mosaicism (a mixture of cells with normal and abnormal chromosomes, which indicates that the fetus may not match the chromosome in the DNA screened from the placenta) or other reasons.
5. The test cannot be performed on mothers carrying more than two babies (triplets or more), mothers carrying multiple babies (twins or more) where there is also an egg donor or surrogate, vanishing twin pregnancies or where the mother had a prior bone marrow or solid organ transplant.

CONSENT

Storage and the supplementary use of surplus test material (your DNA sample) and the test results (the genetic data)

1. **I consent to my personal data and DNA sample being forwarded to the partner laboratory to carry out the test(s)**
2. **I consent to the surplus DNA sample being stored in an anonymised form by the partner laboratory for either quality assurance and/or research purposes.**
3. **I consent to my genetic and clinical data being stored in an anonymised form by the partner laboratory internal reference database, quality assurance and/or research purposes for use in medical or technology advancement.**

PLEASE NOTE: You are allowed to withdraw your consent granted for the storage of personal information, your DNA sample or genetic data and may contact the data protection officer in this regard at any time at **nipt.precise@mediclinic.co.za**. Refusal to permit the use of the sample for research purposes will not affect your test result.

PATIENT

Signature:

Date: D D M M Y Y Y Y

HEALTHCARE PROVIDER

Signature:

Date: D D M M Y Y Y Y

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