Western Diagnostic PATHOLOGY

Generation
a new era in prenatal testing

Lab ID

Non-Invasive Prenatal Test Request Form

Patient Information

Surname: .....

First Name: .....

DOB: D D M M Y Y Y Y Phone: .....

Address: .....

..... Postcode: .....

Email: .....

Patient Consent

By signing this form, I, the patient having the testing performed, acknowledge that: (i) I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits, risks, and limitations of the test to be performed; (ii) I have discussed with the healthcare provider ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for a given disease or condition serves as a predictor of that disease or condition; (iii) I have been informed about the availability and importance of genetic counseling and have been provided with information identifying an appropriate healthcare provider from whom I might obtain such counseling; (iv) I have received and read the Patient Informed Consent in its entirety and realize I may retain a copy for my records; (v) I consent to the use of the leftover specimen and health information as described in the Patient Informed Consent; (vi) I consent to having this test performed and I will discuss the results and appropriate medical management with my healthcare provider.

☐ I wish to receive a rebate voucher for cord blood stem cell storage from Cell Care Australia. I consent to my contact details (and no clinical information) being shared with Cell Care Australia so that I can receive information about cord blood and tissue storage as well as my rebate voucher.

Patient Signature: ..... Date: .....

Requesting Doctor to Sign

Name: .....

Address: .....

..... Postcode: .....

Phone: ..... Fax: .....

Dr Provider No. .....

I confirm the patient has been counselled on the purpose, scope and limitations of the test and has given consent.

Signature: .....

Report Copy Doctor

Name: .....

Address: .....

..... Postcode: .....

Phone: ..... Fax: .....

Test Requested

Step 1: Select **ONE** Generation test:

☐ **Generation**
- T21, T18, T13 & specific sex chromosome aneuploidies

Sex Chromosome aneuploidies is not available for twins

Regional WA & NT: collection Monday-Thursday only

☐ **Generation 46**
- Chromosomal and subchromosomal aneuploidies of chromosomes 1-22 & specific sex chromosome aneuploidies

Sex Chromosome aneuploidies is not available for twins

Regional WA & NT: collection Monday-Thursday only

☐ **Generation Plus** *(not available for twins)*
- T21, T18, T13 & specific sex chromosome aneuploidies
- Microdeletions (See overleaf)

Metro WA: collection Monday am/pm & Tuesday am only
Regional WA & NT: collection Monday am only

Step 2: Indicate whether fetal sex is required:

Fetal Sex identification:

I want fetal sex results included in this report ☐ **YES** ☐ **NO**

If you do not tick one of the boxes above fetal sex results WILL automatically be included in the report. *Fetal sex identification is not available for twins.*

Test Indications

Choose at least one:

☐ Maternal chromosomal abnormality (specify in Clinical Details)

☐ IVF Pregnancy

☐ Recurrent miscarriage/pregnancy loss

☐ Advanced Maternal Age

☐ Positive Serum Screen /High risk CFTS

☐ Abnormal Ultrasound

☐ Hx suggestive of increased risk for the specified chromosome aneuploidies

☐ Patient Request

☐ Other (specify in Clinical Details)

Clinical Details

EDD (mandatory): D D M M Y Y

No. of fetuses: ☐ Singleton ☐ Twin

Comments: .....

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This prenatal test is validated for singleton and twin pregnancies with gestational age of at least 10 weeks 0 days, as estimated by last menstrual period, crown rump length, or other appropriate method (equivalent to 8 weeks fetal age as determined by date of conception).

Do not send reports to My Health Record ☐

DATA ENTRY INSTRUCTIONS: **BILL CODE:** NIPT **PANEL CODE:** **Generation** NIP **Generation 46** NAA **Generation Plus** NPX

Payment Information - This test is NOT covered by Medicare or Private Health Funds.

- Full payment is required prior to blood collection
- Go to **generationnipt.com.au** to pay online and locate a Generation collection centre
- Call 1800 822 999 (Mon-Fri, 8am-6pm AEST) for enquiries or assistance

Receipt Number: .....

PERSON COLLECTING SPECIMEN TO COMPLETE:

I certify I established the identity of the patient named on this request, collected and immediately labelled the accompanying specimen with the patient's details.

Initials: ..... ACC Code / Location: ..... Date of draw: D D M M Y Y Time: : am / pm

Patient Informed Consent

Introduction. This form describes the benefits, risks, and limitations of this screening test. Read this form carefully before making your decision about testing. It is recommended that you seek genetic counselling prior to undergoing this testing. More information regarding this test is available at www.genomicdiagnostics.com.au

Purpose. The purpose of this tests is to screen your pregnancy for chromosomal abnormalities, that cause too many or too few copies of all or part of a chromosome. Depending on the Generation test chosen, screening includes common trisomies 21, 18 and 13, with options for screening for all autosomes (chromosomes 1 to 22), sex chromosomes and microdeletions.

Your options. There are three Generation tests available. Generation screens for the common trisomies (chromosomes 21, 18 & 13), as well as specific sex aneuploidies.
Generation Plus includes these plus 5 microdeletion syndromes - 22q11 deletion (DiGeorge), 15q11 deletion (Angelman/Prader-Willi), 1p36 deletion, 4p- (Wolf-Hirschhorn) & 5p- (Cri-du-chat). Generation 46 screens for chromosomal and subchromosomal aneuploidies of chromosomes 1-22 & specific sex chromosome aneuploidies.

Test Procedure. Payment for your NIPT is required prior to having your blood collected. Collection centre locations are available online when you pay for your test. No booking is required. A tube of your blood will be drawn at your most convenient centre and sent to Genomic Diagnostics, a wholly Australian owned and operated business, where it will be analysed and the results sent back to your doctor. Generation Plus tests are analysed at an accredited laboratory in California, USA.

How this Test Works. This test is not intended to be performed prior to the 10th week of pregnancy, as estimated by last menstrual period, crown rump length, or other appropriate method. The test screens for specific chromosomal abnormalities by looking at the DNA (genetic material) in your blood. To determine whether too few or too many chromosomes are present, this test uses a technology called 'massively parallel DNA sequencing' to count the number of copies of the specific chromosomes, and then uses a proprietary method to determine if there are too many or too few copies of the chromosomes in your pregnancy.

Sex of Pregnancy. Depending upon what your healthcare provider orders, the test results may include the sex of the pregnancy. If you do not wish to know the sex, please tell your healthcare provider to indicate this by ticking the appropriate box under Fetal Sex identification in the Test Menu Options section of the request form. Depending upon the test ordered you may not be able to prevent learning the sex of your pregnancy. In rare instances (<1%), incorrect fetal sex results can occur due to either technical or biological reasons.

Limitations of the Test. This is a screening test that only looks for the specific chromosomal abnormalities tested for. This means other untested chromosomal abnormalities may be present and could cause health concerns. This test does not test the health of the mother, although in some rare cases some high risk test results may be due to chromosomal changes in the mother and may require further investigation. If definitive diagnosis is desired, chorionic villous sampling or amniocentesis should be considered. Normal test results do not eliminate the possibility that your pregnancy may have other chromosomal abnormalities, birth defects, or other conditions, such as open neural tube defects. In addition, a normal result does not guarantee a healthy pregnancy or baby. This test, like many screening tests, has limitations including false positive and false negative rates. 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 it was not really present (this is called a "false positive"). For these reasons it is strongly recommended that no irreversible clinical decisions be made based on these screening results alone. Further testing of the pregnancy and in some cases you, may be needed to confirm your test results which could result in additional expense to you and additional invasive testing procedures (e.g., amniocentesis or chorionic villus samples).

Privacy. We keep test results confidential. Your test results will only be released to your requesting healthcare provider or to another healthcare provider as directed by you, or otherwise as required or authorised by applicable law.

Use of Information and Leftover Specimens. In accordance with best practices and clinical laboratory standards, leftover de-identified specimens (unless prohibited by law) as well de-identified genetic and other information learned from your testing may be used by Genomic Diagnostics for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement.
All such uses will be in compliance with applicable law. Collection of information regarding your pregnancy after testing is part of a laboratory's standard practice for quality purposes. Genomic Diagnostics may contact your health provider to obtain this information.

Test Results. Your test results will be sent to the healthcare provider that ordered the test. Speak with them if you would like a copy of the test results. Your healthcare provider is responsible for interpreting the test results and explaining the meaning to you. Genomic Diagnostics does not provide genetic counselling services directly to patients but can refer you to a counselling service if you would like to avail yourself of this.

Contact Details. By ticking the box under Patient Consent, I agree to receive a cord blood stem cell storage rebate voucher valued up to $250 from Cell Care Australia. I consent to my contact details (but no clinical information) being shared with Cell Care Australia so that I can receive information about cord blood and tissue storage as well as my rebate voucher.

For more information, contact us at info@genomicdiagnostics.com.au

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