

## Healthcare provider information

Referring healthcare provider:		Labcode/Healthlink code:	
Email address: <i>Must include referrers email to receive results</i>	Phone:	Practice name:	
Address:		City:	Post code:

The prenatal screen is validated for singleton and twin pregnancies with gestational age of at least 10 weeks 0 days.

## Choose either singleton or twin

- Singleton pregnancy
- Twin pregnancy
- Monochorionic
- Dichorionic

## Screen indications

## Choose at least one:

- Advanced maternal age
- Positive serum screen

Result:

- Abnormal ultrasound
- Hx suggestive of increased risk for chromosomal aneuploidy
- Low risk
- Maternal choice/anxiety
- Other:

## Clinical information

Gestation age: (wks/days) on (dd/mm/yyyy)  
*Must be ≥ 10 weeks gestation*

## Dating method:

- LMP
- CRL
- Other:

Maternal height:

Maternal weight:

## Healthcare provider consent

I certify that (i) this screen is medically necessary, (ii) the patient (or authorised representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorisation when required by law) to have this screening performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law and Illumina's Patient Informed Consent. I agree to provide Illumina, or its designee, any and all additional information reasonably required for this screening to be performed.

SIGN HERE



Healthcare provider signature:

Date:

## Patient information

First name:		Last name:	
Date of birth: (dd/mm/yyyy)	NHI:	Phone:	

## Patient consent

By signing this form, I, the patient having the screening 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 screen to be performed; (ii) I have discussed with the healthcare provider ordering this screen the reliability of positive or negative screen results and the level of certainty that a positive screen 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 counselling and have been provided with information identifying an appropriate healthcare provider from whom I might obtain such counselling; (iv) I have received and read the patient informed consent in its entirety and realise 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 screen performed and I will discuss the results and appropriate medical management with my healthcare provider.

SIGN HERE



Patient signature:

Date:

Sample will not be processed without the patient's signature

**Introduction** – This form describes the benefits, risks, and limitations of this screen. You should seek genetic counselling prior to undergoing this screening. Read this form carefully before making your decision about screening.

**Purpose** – To screen your pregnancy for certain chromosomal conditions, such as too many or too few copies (this is called an “aneuploidy”). This screen 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 (equivalent to 8 weeks fetal age as determined by the date of conception). Your healthcare provider has determined that this screen is appropriate for you. Consult your healthcare provider for more information about this screen, including the limitations and risks of this screen, performance data, and error rates, descriptions of the common aneuploidies and sex chromosome aneuploidies, and what the screen results may mean to you.

**How this screen works** – It screens for specific chromosomal conditions 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** – The results will include the sex of the pregnancy. If you do not wish to know the sex, please tell your healthcare provider not to disclose it to you. In rare instances, incorrect fetal sex results can occur.

**Limitations of the screen** – This is a screen that only looks for specific chromosomal conditions. This means other chromosomal conditions may be present and could cause health concerns. This screen does not test the health of the mother. Normal screen results do not eliminate the possibility that your pregnancy may have other chromosomal conditions, 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 screen, like many others, has limitations, including false positive and false negative rates. This means that the chromosomal conditions being screened 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 conditions being screened for, even though it was not really present (this is called a “false positive”). Further screening of the pregnancy and in some cases you, may be needed to confirm your results which could result in additional expense to you and additional invasive testing procedures (e.g., amniocentesis or chorionic villus samples). We recommend that no irreversible clinical decisions be made based on these screening results alone. If definitive diagnosis is desired, chorionic villous sampling or amniocentesis would be necessary. Consult your healthcare provider for more information about the limitations of this screen, including error rates (false positives and false negatives). Genetic counselling before and after screening is recommended.

**Screen procedure** – A tube of your blood will be drawn and sent to Labtests Auckland, who will then analyse your blood.

**Physical risks** – Side effects of having blood drawn are uncommon but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection.

**Pregnancy outcome information** – Collecting information on your pregnancy after screening is part of a laboratory’s standard practice for quality purposes. As such, Labtests or its designee may contact your healthcare provider to obtain this information.

**Incidental findings** – In the course of performing the analysis for the indicated screen, information regarding other chromosomal alterations may become evident (called Incidental Findings). Our policy is to NOT REPORT on any Incidental Findings that may be noted in the course of analysing the screen data.

**Privacy** – We keep screen results confidential. Your results will only be released in connection with the service, to your healthcare provider, their designee, other healthcare providers involved in your medical care, or to another healthcare provider as directed by you (or a person legally authorised to act on your behalf) in writing, or otherwise as required or authorised by applicable law.

**Use of information and leftover specimens** – Pursuant to 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 screening may be used by Labtests or others on its behalf for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable law.

**Research** – We may use your leftover specimen and your health information, including genetic information, in an anonymised or de-identified form (unless otherwise allowed by applicable law) for research purposes. Such uses may result in the development of commercial products and services. You will not receive notice of any specific uses and you will not receive any compensation for these uses. All such uses will be in compliance with applicable law.

**Results** – Your results will be sent to the healthcare provider that ordered the screen. Speak with them if you would like a copy of the results. Your healthcare provider is responsible for interpreting the results and explaining the meaning to you.