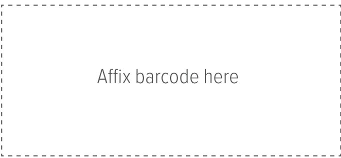

ILLUMI SCREEN

Requisition Form

Ordering Clinician

Referring clinician:			Labcode:
Practice name:	Address:		
	City:	Country:	Postcode:

Phone:	Fax:	Email:

Patient Information (Attach face sheet or label when available)

Last name:	First name:	DOB: dd / month / yyyy	Sex:	NHI:
Address:		City:		Postcode:

Phone:	Fax:	Email:

Illumiscreen Test Menu Options

Choose either Singleton or Twin:

- ☐ For **Singleton** Pregnancy prenatal test for chromosomes 21, 18, 13
  - ☐ Sex chromosome aneuploidies option
  - ☐ Fetal Gender
- ☐ For **Twin** Pregnancy prenatal test for chromosomes 21, 18, 13
  - ☐ Presence of Y chromosome option

Test Indications

Choose at least one:

- ☐ Advanced Maternal Age
- ☐ Positive Serum Screen
- ☐ Abnormal Ultrasound
- ☐ Hx suggestive of increased risk for the specified chromosome aneuploidies
- ☐ Low risk/maternal anxiety
- ☐ Other ______

Illumiscreen Test Menu Options

Gestational age:
wks / days on dd / month / yyyy

Dating method: ☐ LMP ☐ CRL ☐ Date of implantation ☐ Other ______

Maternal height: ______ ☐ cm ☐ ft in

Maternal weight: ______ ☐ kgs ☐ lbs

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).

I certify that (i) this test 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 testing 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 testing to be performed.

Healthcare provider signature: ______ Date: ______

Billing Information

Account name:
HEALTHSCOPE NEW ZEALAND

Contract #:
VHI 018499

Date of draw: dd / month / yyyy

Collection centre:

Collector name:

Paid ☐ Invoice No: ______

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 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 test performed and I will discuss the results and appropriate medical management with my healthcare provider.

Tick here to opt out of Testsafe ☐

SIGNATURE REQUIRED SAMPLE WILL BE DISCARDED IF NOT COMPLETE.

Patient signature: ______ Date: ______

ILLUMI
SCREEN

Patient Informed Consent

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

Purpose. The purpose of this test is to screen your pregnancy for certain chromosomal abnormalities, such as too many or too few copies (this is called an "aneuploidy") of chromosomes 21, 18, 13 as well as the sex chromosomes (X and Y). 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 (equivalent to 8 weeks fetal age as determined by the date of conception). Your healthcare provider has determined that this test is appropriate for you. Consult your healthcare provider for more information about this test, including the limitations and risks of this test, performance data, and error rates, descriptions of the common aneuploidies and sex chromosome aneuploidies, and what the test results may mean to you.

How this Test Works. This 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 not to disclose it to you. Depending upon the test ordered you may not be able to prevent learning the sex of your pregnancy. In rare instances, incorrect fetal sex results can occur.

Limitations of the Test. This is a screening test that only looks for specific chromosomal abnormalities. This means other chromosomal abnormalities may be present and could cause health concerns. This test does not test the health of the mother. 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 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"). 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). 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 test, including error rates (false positives and false negatives). Genetic counselling before and after testing is recommended.

Test 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 testing 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 tests, 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 test data.

Privacy. We keep test results confidential. Your test results will only be released in connection with the testing service, to your healthcare provider, his or her 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 testing 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.

Test Results. Your test results will be sent to the healthcare provider that ordered the test. Speak with him/her 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.