VCGS Leaders in Genetic Health

percept™ cell-free DNA prenatal test

Victorian Clinical Genetics Services
Murdoch Childrens Research Institute
The Royal Children's Hospital
Flemington Road, Parkville VIC 3052
P (03) 8341 6201 F (03) 8341 6366
W vcgs.org.au

1. PATIENT INFORMATION

LAST NAME | GIVEN NAMES | DATE OF BIRTH (dd/mm/yyyy) | LABORATORY REF

ADDRESS | POSTCODE | PHONE (home) | MOBILE

2. CLINICAL INFORMATION

GESTATIONAL AGE: as of date:

DUE DATE by scan (dd/mm/yyyy):

MATERNAL WEIGHT (kg):

MATERNAL HEIGHT (cm):

3. TEST INDICATIONS

- ☐ percept™ AS PRIMARY SCREENING TEST
- ☐ ADVANCED MATERNAL AGE (≥37 YEARS)
- ☐ COMBINED FIRST TRIMESTER SCREEN RESULT
  T21: 1/_____ T18: 1/_____ T13: 1/_____
- ☐ ULTRASOUND ABNORMALITY: _____
- ☐ OTHER: _____

4. TEST OPTIONS

☐ **Singleton** pregnancy
Tests for chromosomes 21, 18, 13, X and Y

Fetal sex is always reported. Clinician to disclose to patient on request.

☐ **Twin** pregnancy
Tests for chromosomes 21, 18, 13 and presence or absence of Y.

Sex chromosome aneuploidy cannot be detected in twins. Fetal sex is always reported. Clinician to disclose to patient on request.

This test is validated for singleton and twin pregnancies of at least 10 weeks gestational age (by scan).

5. REQUESTING DOCTOR

NAME & PROVIDER #:

ADDRESS:

I verify that the patient and prescriber information in this form is complete and accurate to the best of my knowledge.

DOCTOR SIGNATURE AND DATE

_____ DATE: ____/____/____

6. PATIENT CONSENT

By signing this form, I request that VCGS perform the percept™ prenatal test. I have read the patient consent included on the back of this form. The risks and limitations of this test have been adequately explained to me.

PATIENT SIGNATURE AND DATE

_____ DATE: ____/____/____

COPY REPORTS TO:

PHLEBOTOMIST DETAILS:

COLLECTOR SIGNATURE SPECIMEN DATE & TIME (hrs)

7. PAYMENT DETAILS

Credit card details must be completed otherwise test results will not be available. If the payment fails, you will be contacted to verify and/or make payment by another method. If payment is not confirmed within 72 hours, the test will not be processed and a new sample will be required.

CARD TYPE ☐ VISA ☐ MASTERCARD AMOUNT TO BE DEBITED ☐ percept™ prenatal test $ AU449

NAME ON CARD _____ SIGNATURE _____

CARD NUMBER ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ EXPIRY DATE ☐☐ ☐☐

Patient Informed Consent

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Genetic counselling with a VCGS genetic counsellor (03 8341 6201) is available to anybody considering or undergoing this screening test. VCGS genetic counsellors can also discuss other prenatal screening and testing options with you. More information about this test and the chromosome conditions included in the test is available at vcgs.org.au/perceptNIPT

Patients undergoing non-invasive prenatal testing should be aware of the following key points:

Purpose of the test

- This test will identify whether a pregnancy is at 'high-risk' for trisomy 21, trisomy 18 and trisomy 13.
- This test may also identify if the fetus has too many, or too few, of the sex chromosomes (X and Y). The test results will include the sex of the pregnancy. If you do not wish to know the sex you can ask your healthcare provider not to disclose it to you. However, if the fetus has too many, or too few, of the sex chromosomes, you may not be able to avoid learning the sex of your pregnancy.

Test process

- This test is only intended to be performed from the 10th week of pregnancy, as determined by a dating scan. We cannot test before 10 weeks, even if only by one day.
- A sample of your blood will be collected and sent to VCGS who will issue a report to your healthcare provider. Your healthcare provider is responsible for interpreting and explaining your test results. VCGS genetic counsellors are also available to discuss your results with you.
- As this is a screening test, it is recommended that all high-risk test results are confirmed by CVS or amniocentesis.

Limitations of the test

- This test can only detect extra or missing copies of fetal chromosomes 21, 18, 13 and the sex chromosomes (X and Y). This test will not detect any other fetal chromosome abnormalities.
- 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. A 'low-risk' result does not guarantee a healthy pregnancy or baby.
- As this is a screening test, there is a small possibility that the results could be incorrect. It is possible that the chromosomal abnormality being tested for could be present even if the result is low-risk. This is called a 'false negative'. It is also possible to receive a high-risk result even though an abnormality is not really present. This is called a 'false positive'.
- Some high risk test results may be due to chromosomal changes in the mother. Further testing of the mother may be required in some circumstances.
- The ability of this test to accurately report fetal sex chromosome abnormalities (too many or too few sex chromosomes) is not well known. Incorrect test results may occur more frequently for these abnormalities.
- For technical and biological reasons, the fetal sex is reported with >99% accuracy (not 100%).

Privacy, confidentiality and use of information

- Your test results will be kept confidential. Results will only be released to your healthcare provider, other healthcare providers involved in your medical care, or to another healthcare provider as directed by you, or otherwise as required or authorised by applicable law.
- Collecting information on your pregnancy after testing is part of our laboratory's standard practice for quality purposes and test evaluation. VCGS may contact your healthcare provider to obtain this information.

Retention and use of samples

- In line with best practices and clinical laboratory standards, leftover de-identified specimens (unless prohibited by law), de-identified genetic material, as well as other information learned from your testing, may be used by VCGS for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable law.

Financial responsibility statement

- You are responsible for fees incurred with VCGS for services performed.

Wellington Regional Genetics Laboratory

Level 6, Ward Support Block, Wellington Hospital,
Riddiford Street, Newtown, Wellington, 6021, New Zealand

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CARD TYPE ☐ VISA ☐ MASTERCARD AMOUNT TO BE DEBITED NZ$ 55.00 inc. GST

NAME ON CARD _____ SIGNATURE _____

CARD NUMBER ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ EXPIRY DATE ☐☐ ☐☐

Phlebotomy: 1 x 10ml blood sample, inverted.

Please send sample to Wellington Regional Genetics Laboratory, Level 6, WSB, Wellington Hospital

CCDHB Acct. No. 0530-1877

VCGS: Please send results to referring clinician and copy to WRGL: fax: 006443855822 email: Prenatal.Wrgl@ccdhb.org.nz