4Cyte Pathology | percept nipt

Tel: 13 42 98
www.4cyte.com.au

1. PATIENT DETAILS

LAST NAME | GIVEN NAME | DATE OF BIRTH | LABORATORY REF

ADDRESS | POST CODE | PHONE (HOME) | MOBILE

MEDICARE NUMBER *(FOR MY HEALTH RECORD ONLY - NO MEDICARE REBATE)*

☐ Do not send to My Health Record (vcgs.org.au/mhr-policy)

2. TEST REQUESTED

percept non-invasive prenatal test
7-10mL blood in Streck tube

Tests for whole chromosome changes of all 23 chromosome pairs (inclusive of 21, 18, 13, X and Y) and copy number changes ≥ 7 Mb for chromosomes 1-22. Where detected, certain clinically significant copy number changes < 7 Mb are reported.

3. CLINICAL INFORMATION

☐ SINGLETON ☐ TWIN ☐ TRIPLET

GESTATIONAL AGE: _____ as of date: _____

Gestation must be at least 10 weeks at collection; 12 weeks for triplets

EDD: (dd/mm/yyyy): _____

MATERNAL WEIGHT (kg): _____

MATERNAL HEIGHT (cm): _____

4. TEST INDICATIONS

☐ *percept* AS PRIMARY SCREENING TEST

☐ COMBINED 1ST TRIMESTER SCREENING RESULT

T21: 1/_____ T18: 1/_____ T13: 1/_____

☐ ULTRASOUND ABNORMALITY: _____

☐ KNOWN TRANSLOCATION CARRIER (prior lab assessment required)

Specify: _____

☐ OTHER: _____

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

DOCTOR'S SIGNATURE AND REQUEST DATE

SIGNATURE: DATE:

COPY REPORTS TO:

5. REQUESTING DOCTOR (PROVIDER #, INITIALS, ADDRESS, EMAIL)

Email:

6. PATIENT CONSENT

I consent to VCGS performing the *percept* prenatal test.
I have read the patient consent on the back of this form.
The risks & limitations of this test have been explained to me.

I understand there are no cancellations or refunds (except if test fails).
I agree to pay the cost of this test in full as outlined at **vcgs.org.au/percept-process**

PATIENT SIGNATURE AND DATE

SIGNATURE: DATE:

NOTES:

This test is validated for pregnancies of at least 10 weeks gestational age.
Fetal sex is always reported. Clinician to disclose to patient on request.
Sex chromosome aneuploidy cannot be detected in twins/triplets.

PHLEBOTOMIST DETAILS:

Time of collection:

Date of collection:

SIGNATURE:

Place of collection:

7. PATIENT PAYMENT INFORMATION

NIPT is **NOT** covered by Medicare or private health insurance. There is an out-of-pocket cost.

Testing
We will test your sample as soon as it arrives at VCGS, even if you haven't received the SMS payment link.

Results
Results will be sent to your healthcare provider when available.
This is usually 3-5 working days after your sample has arrived at VCGS.

Payment
We will send an SMS link to make payment. This usually happens a few working days after we receive your sample.
Ignoring the payment SMS will not cancel your test.

Please read important information about test process and payment:

vcgs.org.au/percept-process

Customer Care team: 1300 118 247

VCGS leaders in genetic health

Genetic counselling with a VCGS genetic counsellor (03 9936 6402) is available to anybody considering this screening test. VCGS genetic counsellors can also discuss other prenatal screening and testing options with you. More information about this test is available at vcgs.org.au/percept-NIPT

Patients having *percept* non-invasive prenatal testing should be aware of the following key points:

Purpose of the test

This test identifies pregnancies with an increased chance of:

- Trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome);
- Sex chromosome differences (extra or missing copies of chromosomes X and Y);
- Rare autosomal trisomies (those involving chromosomes other than 21, 18, 13, X and Y);
- Extra or missing parts of chromosomes (usually ≥ 7 Mb in size) that may be associated with health concerns.
- Certain extra or missing parts of chromosomes < 7 Mb in size, that are associated with health concerns.

percept NIPT can be used to screen pregnancies where a parent is a known translocation carrier. This requires prior arrangement with the laboratory.

Test process

- This test is intended to be performed from the 10th week of pregnancy onwards, ideally determined by a dating ultrasound.
- Your blood sample will be sent to VCGS for testing and a report will be issued to your healthcare provider. They are responsible for interpreting and explaining your test results. The VCGS reproductive genetic counselling team are also available to discuss results with you.
- The test results will include the sex of the developing baby. Let your healthcare provider know if you do not want to know the sex.
- If the results show sex chromosome differences, the sex of the developing baby may be revealed.

Limitations of the test

- This test screens for extra or missing copies of whole chromosomes or parts of chromosomes in the developing baby. It is NOT designed to detect all chromosome imbalances, 22q11.2 deletions, single gene disorders or non-genetic causes of fetal abnormalities.
- NIPT will not tell you for certain if your developing baby has a chromosome condition. It is recommended that prenatal diagnostic testing (via CVS or amniocentesis) is offered for increased chance test results.
- Low chance test results reduce but do not eliminate the possibility your pregnancy has a chromosome condition. A low chance result does not guarantee a healthy pregnancy or baby.
- With this screening test it is possible to receive an increased chance result even if the developing baby does not have a chromosome condition. This is called a 'false positive' result. It is also possible that the developing baby may have a chromosome condition even if you receive a low chance result. This is called a 'false negative' result.
- Some test results may suggest chromosomal changes in the mother. Further testing of the mother may be recommended. In some cases, these findings may have health impacts for the mother.
- Fetal sex is reported with >99% accuracy (not 100%), due to test limitations. Sex chromosome differences cannot be assessed in twin and triplet pregnancies.
- The ability of this test to screen chromosome conditions in triplet pregnancies is not well known. False test results may occur more frequently.
- Please let your healthcare provider know if you're a recipient of an organ donation or you've had a bone marrow transplant. This may affect sex chromosome reporting.

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 health information after testing enables ongoing test evaluation to improve performance and service delivery. VCGS may contact your healthcare provider to obtain this information.
- Your de-identified genetic and health information may be shared to advance scientific knowledge, for ethically approved medical research and to educate health professionals via scientific presentations, publications, and educational resources.

Retention and use of samples

- In line with best practices and clinical laboratory standards, leftover de-identified samples, de-identified genetic material, as well as other information learned from your testing, may be used by VCGS. Use may include quality control, laboratory operations and improvement, test development, and generation of new scientific knowledge. All use will comply with applicable law.

Financial responsibility statement

- You are responsible for the cost of this test. There are no cancellations or refunds - except if the test fails.
- Information about test process and payment can be found on our website – vcgs.org.au/percept-process