

1. PATIENT DETAILS

LAST NAME	GIVEN NAMES	SEX	DATE OF BIRTH	YOUR REFERENCE
ADDRESS		POST CODE	PHONE (home)	MOBILE

2. TESTS REQUESTED

Combined first trimester screening (CFTS) or second trimester maternal serum screening (2TMSS)

5-10mL clotted blood sample. Gel or plain tube - NO ANTICOAGULANT

- CFTS (sample @9-13W6D) 2TMSS (sample @14-20W6D)
 CFTS + PE (sample @11-13W6D) 2TMSS + NTD (sample @15-20W6D)
early onset pre-eclampsia neural tube defects
 family history of PE YES NO family history of NTD YES NO
 first pregnancy YES NO

The requesting doctor should ensure both blood specimen & ultrasound reports are provided to the maternal serum screening lab for a complete combined first trimester screening result.

3. CLINICAL INFORMATION

LMP: ____/____/____

CLINICAL DUE DATE: ____/____/____

GESTATIONAL AGE: ____ ON ____/____/____

U/SOUND DUE DATE: ____/____/____

MATERNAL WEIGHT: _____ kg

MATERNAL BP: SP ____/DP ____ mmHg

PREVIOUS: T21 NTD Pre-eclampsia

SD

State the patient's status at the time of the service or when the specimen was collected:

4. CLINICAL NOTES

- IVF own egg pick-up date ____/____/____ donor egg DOB ____/____/____ pick-up date ____/____/____
 Diabetes (IDDM only) Smoker Threatened miscarriage Twins
 Ethnic group: European Aboriginal Asian Afro-Caribbean Other: _____

5. ULTRASOUND

Name of imaging practice: _____

Date of ultrasound: ____/____/____

REQUESTING DOCTOR (provider #, initials, address):

PATIENT TEST AND FINANCIAL CONSENT

I consent to VCGS performing maternal serum screening.

Financial acknowledgement
I understand there is only a partial Medicare rebate for this test for eligible patients. There will be some out of pocket cost. An invoice will be sent for the full amount. You can then claim your rebate from Medicare after the invoice has been paid. Cost information can be found at vcgs.org.au/maternal-serum-screening

Medicare Assignment
(Section 20A of the Health Insurance Act 1973) I offer to assign my right to benefits to the approved pathology practitioner who will render the requested pathology service(s) and any eligible pathology determinable service(s) established as necessary by the practitioner.

PATIENT'S SIGNATURE AND DATE

SIGNATURE: _____ DATE: _____

DOCTOR'S SIGNATURE AND REQUEST DATE

SIGNATURE: _____ DATE: _____

COPY REPORTS TO:

SPECIMEN COLLECTION

I CERTIFY THAT THE PATHOLOGY ACCOMPANYING THE REQUEST WAS COLLECTED FROM THE PATIENT STATED ABOVE AS ESTABLISHED BY DIRECT INQUIRY AND/OR INSPECTION OF WRIST BAND.

PHLEBOTOMIST SIGNATURE: _____

COLLECTION DATE: ____/____/____ COLLECTION TIME (hrs): _____

PATIENT COPY

LAST NAME	GIVEN NAMES
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TESTS REQUESTED
Maternal Serum Screening Test (MSST)

CFTS (sample @9-13W6D) 2TMSS (sample @14-20W6D)
 CFTS + PE (sample @11-13W6D) 2TMSS + NTD (sample @15-20W6D)
early onset pre-eclampsia neural tube defects

Patient advisory note
Your doctor has recommended that you use VCGS. You are free to choose your own pathology provider. However, if your doctor has specified a particular pathologist on clinical grounds, a Medicare rebate will only be payable if that pathologist performs the service. You should discuss this with your doctor.

Privacy note
The information provided will be used to assess any Medicare benefit payable for the services rendered and to facilitate the proper administration of government health programs, and may be used to update enrolment records. Its collection is authorised by the provisions of the Health Insurance Act 1973. The information may be disclosed to the Department of Health or to a person in the medical practice associated with this claim, or as authorised/required by law.

Genetic counselling with a VCGS genetic counsellor is available to anyone considering this screening test (1300 118 247). Genetic counsellors can also discuss other prenatal screening and testing options with you. More information about this test is available at vcgs.org.au/maternal-serum-screening

Purpose of the test

VCGS offers screening for some conditions that can be identified during pregnancy. Maternal serum screening has two options: screening during the first trimester or screening during the second trimester.

- **Combined first trimester screening (CFTS):** provides an estimate of the chance that a pregnancy has a chromosome condition such as Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) or Patau syndrome (trisomy 13). An optional extra with CFTS is screening for early-onset pre-eclampsia (EO-PE). Early detection and treatment can improve pregnancy outcomes.
- **Second trimester screening (2ndTMSS):** provides an estimate of the chance that a pregnancy has Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) or a neural tube defect, such as spina bifida.

Test process

CFTS combines a blood test with an ultrasound.

1. A blood test between 9 weeks + 0 days and 13 weeks + 6 days (if having PE as well, blood must be collected between 11 weeks and 13 weeks + 6 days). This measures two proteins called PAPP-A and free beta hCG. These are found naturally in the blood during pregnancy. A change in the level of these proteins may indicate a greater chance of a chromosome condition.
2. A nuchal translucency ultrasound (NT scan). This ultrasound is performed by a specialist ultrasonographer between 11 weeks + 1 day and 13 weeks + 6 days. The ultrasound measures the thickness of a fluid filled space at the back of baby's neck and also the presence or absence of the nasal bone. An enlarged space and/or absence of the nasal bone may indicate a greater chance of a chromosome condition.

The results of the blood test and the NT ultrasound are combined with the patient's age and weight to give a combined estimate of the chance the pregnancy may have a particular condition.

2ndTMSS is a blood test only.

Blood is collected between 14 and 20 weeks. Although if the sample is collected between 14 and 15 weeks, no estimate will be given for neural tube defects.

A list of blood collection sites can be found on our website: <https://collection-sites.vcgs.org.au/>

Limitations of the test

- Maternal serum screening is not a diagnostic test. Therefore, not all pregnancies with a chromosome condition will be identified. Screening only looks for a small number of particular chromosome conditions: no screening test can identify all possible conditions that may affect a pregnancy.
- A screen negative result means it is very unlikely the pregnancy has a chromosome condition. The majority of women will receive a screen negative result. As with all screening tests, there is always a small chance the result is incorrect (false negatives).
- A small number of women will receive a screen positive result. This does not mean the pregnancy definitely has a chromosome condition - only that there is a higher chance. If you receive this result, you will be offered diagnostic testing to confirm the result. In most cases, the screen positive result turns out to be a 'false positive' and the pregnancy does not have the chromosome condition. If you receive a screen positive result, there are two options for further testing. You can have *percept* non-invasive prenatal test (NIPT), which is a more accurate screening test or you can have a diagnostic test. A diagnostic test requires an invasive procedure such as a CVS or amniocentesis.

Privacy, confidentiality & 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 & 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, laboratory improvement, and generation of new scientific knowledge. All such uses will be in compliance with applicable law.

Financial responsibility

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