VirtusGenetics
A MEMBER OF VIRTUS HEALTH

Reproductive Carrier Screen
Request Form

BARCODE

PATIENT INFORMATION:

Patient First Name:

Surname:

Date of Birth: _____/_____/_____ Sex:

Address:

Tel (Mobile):

Medicare No. ☐☐☐☐ ☐☐☐☐☐ ☐

STATE THE PATIENT'S STATUS AT THE TIME OF THE SERVICE OR WHEN THE SPECIMEN WAS COLLECTED:

- ☐ a private patient in a private hospital or approved day hospital facility
- ☐ a private patient in a recognised hospital
- ☐ a public patient in a recognised hospital
- ☐ an outpatient of a recognised hospital

PARTNER INFORMATION: *(if applicable)*

First Name:

Surname:

Date of Birth: _____/_____/_____ Sex:

Address: ☐ (tick if same as patient)

Tel (Mobile):

I consent for my information to be included on my partner's report.

Partner Signature:

Date:

CLINICAL INFORMATION:

Is your patient pregnant? YES ☐ No ☐

Gestational age ..... wks ..... days

OR Estimated due date: D D / M M / Y Y Y Y

Family history of genetic conditions? YES ☐ No ☐

If yes, please provide details below on gene/variant and familial relationship

TESTS REQUESTED:

BASIC CARRIER SCREEN ☐

(CF, SMA, FRX in females; CF, SMA in males) - $400*

*Medicare rebates may apply for part of the test fee. Relevant clinical information must be provided.

EXPANDED CARRIER SCREEN ☐

(289 genes in females, 268 genes in males) - $650 (No rebate applies)

REQUESTING DOCTOR:

Name:

Address:

Phone: Provider No:

I confirm that this patient been counselled about the purpose, scope, and limitations of the test and has provided informed consent for the test.

Doctor Signature:

Date:

COPY REPORTS TO:

Name:

Address:

FOR THE PATIENT:

I confirm that I have been informed about the purpose, scope, and limitations of the test (see overleaf). If I do not fulfil the Medicare criteria, or an out-of-pocket fee applies, I understand and consent to payment of fees.

Medicare Agreement (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 pathologist determinable service(s) established as necessary by the practitioner.

Patient signature:

Date:

Reason for patient being unable to sign *(practitioner use only)*:

FOR THE COLLECTOR:

I certify that I established the identity of the patient named on this request form and collected and immediately labelled the accompanying specimen(s) with the patient's name, DOB, and date/time of collection.

Please collect 1 x 4mL dedicated whole blood EDTA tube. Store sample at room temperature.

Collector name:

1 x 4mL EDTA ☐ Collection time: Date:

Collector signature:

Date:

Your doctor has recommended that you use Virtus Diagnostics. 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.

Test purpose

Reproductive carrier screening assesses the chances of you and your partner having a child affected by the genetic conditions tested. These childhood-onset conditions have been chosen due their potential to significantly impact on quality of life and/or lifespan of an affected child. This information may inform your family planning decisions.

Test procedure

Blood samples will be collected from you, or from both you and your reproductive partner. The basic carrier screen is performed in a NATA-accredited Virtus Diagnostics laboratory. For expanded carrier screening, samples are sent overseas to Invitae (USA) for testing in a CAP-accredited and CLIA-certified clinical laboratory.

Results will be available up to 4 weeks after your sample is received in the laboratory. Results will be issued to the doctor who requested your testing, as well as other healthcare professionals nominated to receive your result. Results will be discussed with you and your partner, and genetic counsellors are available to assist you and your doctor as required.

If only a single partner is being tested first, we recommend testing the female partner. Note that most individuals will be a carrier of at least one genetic condition, often requiring follow-up carrier screening in the male partner.

Test interpretation

There are two potential test results:

1) No genetic variants are identified, or
2) You are a carrier of one or more genetic conditions

If no genetic variants are identified, this reduces the chances of you being a carrier for the conditions tested. This therefore reduces the chances of you and your partner having a child affected by these conditions. However, it does not eliminate this risk.

If you are found to be a carrier, it will be for an 'autosomal recessive' and/or 'X-linked' disorder.

- Autosomal recessive conditions: There is only a risk of having an affected child if both you and your partner are carriers of the same condition. If both of you are found to be carriers, there is a 1 in 4 (25%) chance of having an affected child. Most of the conditions tested are autosomal recessive.
- X-linked conditions: Female carriers of an X-linked condition have up to a 50% chance of having a child with the condition, irrespective of the male partner's test result. Male individuals are not routinely tested for X-linked conditions.

In most circumstances, being a carrier will not have health implications for you, and only increases your risk of having a child affected by a genetic condition. In rare situations, test results may have health implications for your own health, such as revealing an undiagnosed condition or increased risk of a medical condition. Your results may also have implications for your family members.

Test limitations

Carrier screening does not screen for all possible inherited genetic conditions. It therefore does not exclude the possibility of having a child affected by a genetic condition.

Carrier screening will not identify all individuals who are carriers of a genetic condition, and rare genetic variants may be missed. The residual risk of being a carrier may be higher if you have a family history of a genetic condition. Providing details of the specific gene variant(s) present in your family will be useful in assessing this risk.

Only genetic variants that cause or significantly increase risk of disease ('pathogenic' or 'likely pathogenic' variants) will be reported. Benign variants and 'variants of uncertain clinical significance' will not be reported. Result interpretation relies on currently available information in the medical literature and may change over time as new information emerges. Routine data re-interpretation will not be performed.

Rare testing errors may occur. Accurate results may not be obtained for reasons including, but not limited to, sample mix-up, bone marrow transplant, recent blood transfusion, or technical reasons. An additional sample may be requested in some situations.

The results of this test will not affect your access to health insurance. Identifying carrier states through this test is unlikely to affect your ability to obtain life insurance.

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.

For expanded carrier screening, your sample and personal information will be made available to Invitae for the purposes of providing test services and performing related activities, as further described in Invitae's Privacy Policy (*www.invitae.com/privacy*).