

### Patient Details

Last name \_\_\_\_\_

Given name (including middle initial) \_\_\_\_\_

Date of birth \_\_\_\_\_

UMRN \_\_\_\_\_

Address \_\_\_\_\_

Phone number \_\_\_\_\_

Medicare # \_\_\_\_\_

I do not have a Medicare card

#### Patient test and financial consent

By signing, I request that PathWest performs testing AssureUs testing. I have read the consent information (over the page) and have no further questions. I understand there will be an out-of-pocket cost if I am not Medicare-eligible for this test.

I consent to testing

#### Medicare Assignment (Section 20A 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 \_\_\_\_\_

### Results And Records

Patients referred by GPs and private patients must complete the Medicare Assignments details above. To comply with Privacy Act requirements, these patients must also provide consent for genomic test results to be entered into the iCM (below).

DO NOT SEND REPORTS TO MY HEALTH RECORD

#### Results to HDWA Clinical Information System (iCM)

See CIS informed consent information sheet.

I consent for my results to be stored in the iCM.

Patient's Signature \_\_\_\_\_

Date \_\_\_\_\_

### Pathology Provider

Your doctor has recommended that you use PathWest. You are free to use 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.

Specified APP:  Yes  No

APP Name \_\_\_\_\_

### Informed Consent



Please turn over the page and carefully read the information about the purpose of this test, its process and limitations, results, Medicare and financial responsibility and the storage and use of personal information.

### Test Requested

**AssureUs - Female Partner Only** (CF, FXS, SMA)

4mL EDTA or saliva sample where available

### Clinical Information

Pregnant  Not pregnant

EDD (dd/mm/yyyy) \_\_\_\_\_

Do you / your partner have a family history of CF, FXS, SMA or other inherited condition?

Yes  No

Provide details of relationship, gene/variant if known:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### If applicable:

I'm donating egg  sperm   
I'm using donor egg  sperm  embryo

### Requesting Doctor

(Surname, initials, provider #, address, phone and fax (fax number required to receive a copy of the report).

\_\_\_\_\_  
\_\_\_\_\_

I confirm informed consent has been obtained for testing

Doctor's Signature \_\_\_\_\_

Request Date \_\_\_\_\_

### Copy Reports To

(Surname, initials, provider #, address, phone and fax (fax number required to receive a copy of the report).

\_\_\_\_\_  
\_\_\_\_\_

### Practitioner's Use Only

Reason patient cannot sign \_\_\_\_\_

### Collector's Signature

#### COLLECT 1x 4mL EDTA sample

I certify that the sample/s accompanying the request was collected from the patient/s above. I established their identity by direct inquiry and/or inspection of the wrist band. I labelled the samples immediately after collection. The patient/s have verified that their name and date of birth on all specimen containers are correct.

Collector's Signature \_\_\_\_\_

Date of Collection \_\_\_\_\_

Time of Collection \_\_\_\_\_

# AssureUs reproductive carrier screening (3 gene)

## 1. About the test

**AssureUs** is a genetic screening test for carrier status for any of the three common genetic disorders cystic fibrosis, fragile X syndrome, and spinal muscular atrophy. While generally healthy, carriers have an increased risk of having a child with the tested conditions. Biological female carriers of a gene variant associated with fragile X disorders may also be at personal risk of reproductive and/or late-onset neurological issues.

Genomic test results are based on current knowledge, which may change in the future. In rare circumstances, issued reports may be changed due to advancement of knowledge.

See our website for additional test information - [pathwest.health.wa.gov.au/assureus](http://pathwest.health.wa.gov.au/assureus)

## 2. Test limitations

**AssureUs** is a screening assay and only common changes in the genes related to cystic fibrosis, fragile X syndrome, and spinal muscular atrophy may be detected. Less common changes in these genes may not be detected. Variants of uncertain clinical significance are generally not reported.

Carrier risk for other genetic/chromosomal disorders cannot be excluded by this test.

Test accuracy is dependent on the provided prior history.

Unless specified on the request form, we assume:

- There is no family history of the tested conditions or any other genetic disorder.
- There is no medical history of transplantation or blood transfusion that can lead to false results.
- You and your partner are not closely or distantly related.

## 3. Results

I understand:

- I will be told the results by a health professional.
- Results are reported to the practitioner ordering the test and any approved recipient(s).
- Genetic test results very rarely change over time and depend on test sensitivity and specificity.
- The report may be included in my electronic medical record.
- Results may have implications for other family members.
- Results from these tests may affect the ability to obtain some types of insurance.
- Results are confidential and may only be released with your consent, or as allowed by law.

## 4. Storage and use of personal information

Your sample is stored in accordance with national standards for a minimum of three months. Stored samples may be used in the future if additional testing is required. De-identified samples may be used for ethically-approved research, quality improvement, or education. You can advise at any point if you do not want your sample to be used in these scenarios or if you would like the sample to be destroyed.

Laboratory records are kept in accordance with laboratory and legal requirements.

De-identified results may be submitted to secure national or international clinical databases helping in continuous improvement of result interpretation.

## 5. Financial consent

**AssureUs** is bulk billed for Medicare eligible patients. Patients not eligible for Medicare will be billed the standard Medicare charge (Item 73451).