AssurePlus
Reproductive Couple Testing

Reproductive Carrier Screening (Expanded Panel) Request
Test Code: GRCSP

LAB No. (PathWest)

Biological Female

Last name

Given name (including middle initial)

Date of birth UMRN

Address

Phone number

Medicare # ☐ I do not have a Medicare card

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

Pregnant? ☐ Yes ☐ No EDD (dd/mm/yyyy)

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

☐ Yes ☐ No

Provide details of relationship, gene/variant if known:

Biological Female - 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

Couple-Based Test And Financial Consent

☐ I/we understand there are out of pocket costs of $850 per couple for this testing. I/we understand that if I/we are not eligible for Medicare we will also be billed the standard Medicare charge for the cystic fibrosis, fragile X syndrome and spinal muscular atrophy assessment which is included in this testing (Item 73451).

Biological Female Signature Date

Biological Male 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, and the out-of-pocket cost may be different if expanded carrier screening is requested. 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.

Biological Male

Last name

Given name (including middle initial)

Date of birth UMRN

Address

Phone number

Medicare # ☐ I do not have a Medicare card

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

Yes ☐ No ☐

Provide details of relationship, gene/variant if known:

Biological Male - 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

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 BOTH SAMPLES AT THE SAME TIME - 1x 4mL EDTA each

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

Diagnostic Genomics
2nd Floor, PP Block
Hospital Avenue, Nedlands
Western Australia 6009
ABN 83 469 340 804

Enquiries
(08) 6383 4234

AssurePlus reproductive carrier screening (expanded panel - couples only)

1. About the test

AssurePlus is a genetic screening test assessing the chance of a reproductive couple of having children with cystic fibrosis, fragile X syndrome, spinal muscular atrophy plus approximately 750 serious childhood-onset conditions across over 1300 genes based on the Mackenzie's Mission Reproductive Carrier Screening Panel.

While generally healthy, carriers have an increased risk of having a baby with the tested conditions. Biological female carriers of a gene variant associated with fragile X disorders may 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/assureplus

2. Test limitations

AssurePlus is a couple-only screening test to determine the combined chance of having a child with a severe childhood-onset genetic disorder. If either of the partners forms a new couple, the test would need to be performed again as each couple has a different chance. If both partners are not available, this test cannot be performed.

This test will identify most couples with an increased chance of having a child with a severe childhood-onset genetic condition associated with the genes screened. Some genetic changes may not be identified due to test limitations. 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

AssurePlus has an out-of-pocket cost of $850 per couple to be paid at time of sample collection. The cost for the screening for cystic fibrosis, fragile X syndrome and spinal muscular atrophy is bulk billed for Medicare eligible patients. The cost for all other screened conditions is out-of-pocket.

Patients not eligible for Medicare will also be billed the standard Medicare charge for the cystic fibrosis, fragile X syndrome and spinal muscular atrophy assessment (Item 73451).