

The "How-To" Guide:

Accessing Reproductive Tests & Resources for your Patients

Presenter: Katelyn Henry





Today's talking points:

1. Overview of RCS, ECS and NIPT and how to access

2

- 2. Genetic counselling for high risk results
- 3. Educational resources available
- 4. Genetic pathologist support and access

Our Reproductive Genetic Tests:

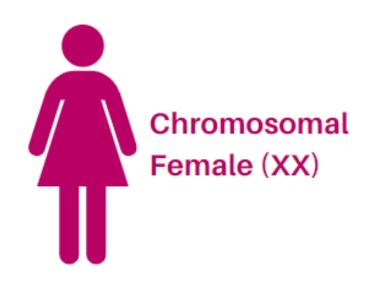
- 3-Gene Reproductive Carrier Screening (CF SMA FRAX)
- Expanded Carrier Screening (430+ genes)
- Non-invasive Prenatal Testing (NIPT) and Genome-wide NIPT (g-NIPT)

3 Gene Reproductive Carrier Screen CF SMA FRAX



Medicare Rebate for 3 Gene Panel

MBS item 73451



Covers the initial screening of the female who is pregnant or planning pregnancy.

Chromosomal Male (XY)

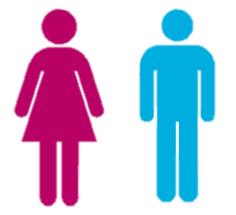
MBS item 73452

Covers the subsequent screening of the male reproductive partner for either CF or SMA, when detected in the female.

Pathways for RCS Testing

SUBSEQUENT

Chromosomal Female (XX) Screen female then screen male if indicated Chromosomal Male (XY)

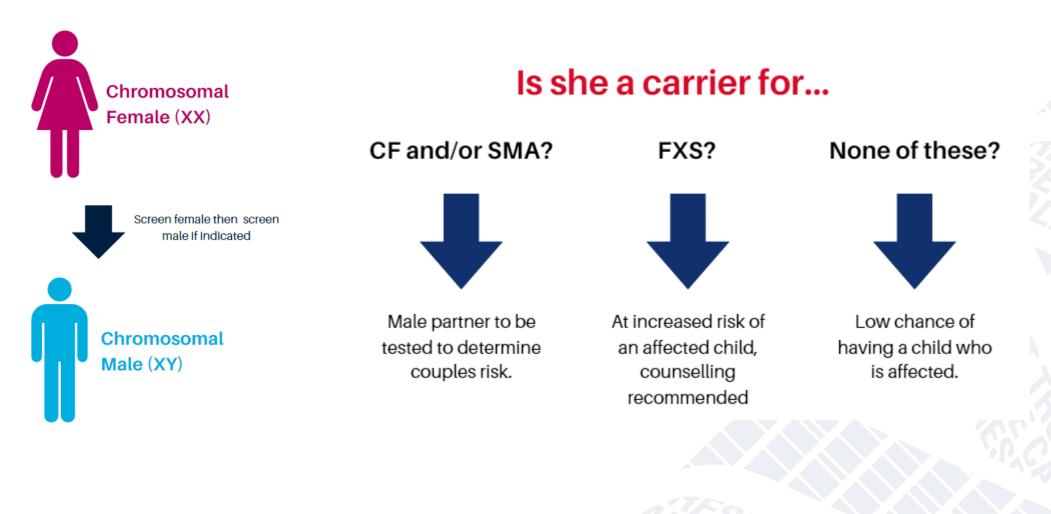


SIMULTANEOUS

Screened at the same time.



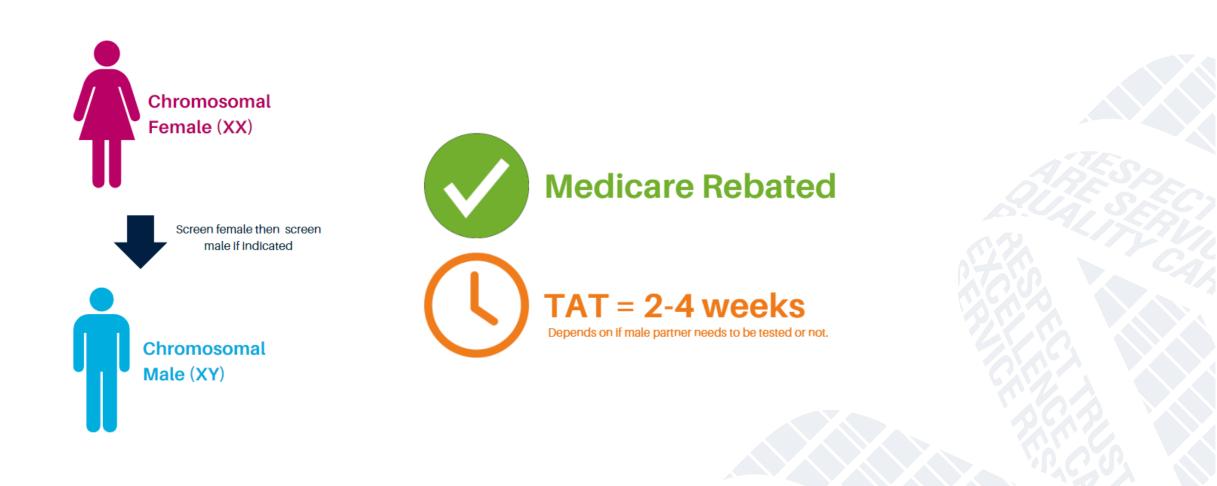
SUBSEQUENT TESTING



7

GP Shared Care GPEX

SUBSEQUENT TESTING



SIMULTANEOUS TESTING

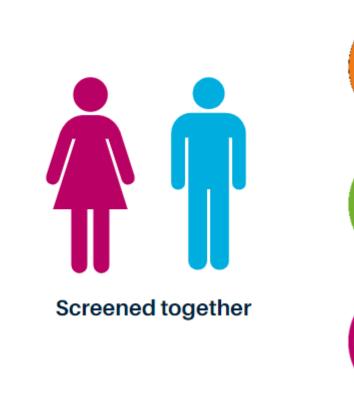


Screened together



April 2024

Pathways for RCS Testing



Partially rebated Female is rebated, male pays \$385 TAT = 2 weeks **Recommended pathway if** couple pregnant





Carrier Couple Identified!

Female is carrier of X-linked FXS **OR** both are carriers of mutations in CF or SMA

1. You will get a report that couple are carriers and at increased risk

2. If female is a FRAX carrier or the couple are carriers of mutations for CF or SMA then they are eligible for one session of genetic counselling through Clinpath / Sonic Genetics*



How do I order the 3 gene carrier screen?



Standard Clinpath form as: "3 gene carrier screen" OR "reproductive screening –genetic test"



Through your e-collect:

"reproductive screening –genetic test", search "REPRO" or set it up as a favourite



Dedicated RCS request form: In BP and MD

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	Me	d icalDire
Sonic Genetics	Sonic Healthcare practices: Cirpan Particiogy Hosen Particiogy Lawranian Parkingy Southern MC Particiogy Southern MC Particiogy	
Reproductive carrier screer	ning Reque	est form
FOR THE DOCTOR	Requesting doct	or
This test should be requested by the doctor responsible-for managing a patient's lecision making reparding the reproductive carrier sovern for cystic fibrosis (CF), pinal muscular atrophy (SMA) and foglie X syndrome (FXS). Please see overleaf for	Name	
Aedicara criteria.	Address	
Patient details		
First name	Phone	Provider No.
Date of birth / Sec at birth Female		DOCTOR SIGNATURE
Address	x	Date
	Copy reports to	
Phone (mobile)	Name	
	Acidress	
PATIENT STATUS AT TIME OF SERVICE OR SPECIMEN COLLECTION (Required by low for all patients) Visa the patients		
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Outpatient of a recognised hospital?	Loorden that I have been	n informed about the purpose, scope and limitations
Test requested	ARDICAR ASSIGNMENT	Section 20And the result learners Act 1973, analysis to the approved pathology practices who will wreak work? and any eligible pathologist determinable service(s) the practices.
Reproductive carrier screen	the respansed pathology ser- webbliehed as recovery by PINANCAL ACKNOWLED	nonen ern ern vilgible particiopat determinable tervionial the practiliones GMENT)
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Clinical information	X	PATIENT SIGNATURE
Pregrant OR Panning pregnancy Please indicate if any known history of CF, SMA or FXS for the:	Precitioner's Line Only Do	ment for patient being strable to sign
Patient/patient's family	For pricing, please which	o our website - sonicgenetics.com.au
Reproductive partner/partner's family I Yes No NA If Yes, please provide details of relationship to this patient and familial	FOR THE COLLEG	
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in the second seco		Pirt & Send Cancel



How do I order partner testing?



Standard Clinpath form as:

"carrier testing, partner carrier of XXXX"

CLINPATH PATHOLOGY	21 James Congdon Drive Mile End SA 6031 ABN 17 088 204 251 Sonic Healthean Limited A.P.A. ABN 24 0 Level 22, Groswanor Place, 225 George St ASW 2000			2000 hours
SURNAME CITZEN ADDRESS	MR, MRS, MISS, MS, DR. MR JAMES	GIVEN NAME(S) SEX DATE (M 01/10, TEL (HOME)		REFERENCE
CLINICAL NOTES	er is a carrier of CF	COPY	COLLECTOR CODE	C R <u>WICAL CYTOLOGY</u> E Cervix
URGENT PHONE PHONE / FAX No.:	FAX 3Y TIME	465XXXXXXX Your doctor has recommanded that you use Citipath. You are here to choose yo However, if your doctor has specified a particular pathologist on dirical ground if that pathologist performs the service. You should discuss this with your doctor Please see reverse for Blood Transfusion and Gynaec DOCTOR'S SIGNATURE AND RE	Ar own pathology provider. a Medicare rebate will only be payable ological Cytology requests.	normal Bleeding
VETERAN'S AFFAIRS GOLD CARD No.:				



How do I order partner testing?



Standard Clinpath form as:

"carrier testing, partner carrier of XXXX"



Partner testing form which is provided in females report





Reproductive Carrier Screening

CONDITION	CARRIER RISK	RESULT
Cystic fibrosis (CF)	CARRIER	Heterozygous CFTR variant detected CFTR:c.1521_1523del, p.(Phe508del)
Fragile X syndrome (FXS)	Low risk	Normal range allele(s) detected FMR1:c129CGG: 29,29
Spinal muscular atrophy (SMA)	Low risk	At least two copies of the SMN1 gene detected

INTERPRETATION

- CF This individual is a carrier of CF and is therefore at increased risk of having a child affected by CF.
- FXS This individual is unlikely to be a carrier of FXS. Residual risk varies with ethnicity and family history.
- SMA This individual is unlikely to be a carrier of SMA. Residual risk varies with ethnicity and family history.

RECOMMENDATION

Discussion of this result and its implications is recommended (see https://www.sonic.fvi/rcs/ for further information). CF carrier testing of the reproductive partner (MBS-rebatable if eligible, see attached) and at-risk family members is recommended. This report should be interpreted in conjunction with the reproductive partner carrier screen result.



TEST INFORMATION

How do I order partner testing?



Standard Clinpath form as:

"carrier testing, partner carrier of XXXX"



Partner testing form which is provided in females report



Reproductive carrier screening partner testing | Request Form

FOR THE DOCTOR

This test is provided to male partners as an extension of our reproductive carrier screening service.

Patient details

First name	 	
Surname	 	
Date of birth	 Sex	Malo
Address	 	
Phone (mobile)	 	
Medicare No.		

PATIENT STATUS AT TIME OF SERVICE OR SPECIMEN	COLLECT	ION	
(Required by law for all patients) Was the patient a:			
Private patient in a private hospital or approved day hospital? Hospital patient in a recognised hospital?	Yes Yes		No No
Private patient in a recognised hospital?	Ves		No
Outpatient of a recognised hospital? Hospital Ward	Ves		No

Test requested

Male partner carrier test for Cystic fibrosis

*This testing is available through

Requesting doctor

	Address		
-			
	Phone		
		hat this patient has been counselled abo ions of the test and has given consent.	out the purpose, scope
	Signatur	e SCDOCTOR SIGNATURE	Date
	Copy rep	orts to	
]]	Copy repo	orts to	
]		orts to	
	Name Address	PATIENT - Patient consent	

MEDICARE ASSIGNMENT (Section 20A of the Health Insurance Act 1973): Loffer 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.

FINANCIAL ACKNOWLEDGMENT:

Lunderstand that (a) the test requested may not qualify for a Medicare rebate and in this circumstance Lagree to meet the cost of the test in full; (b) some tests are not bulk billed and attract a practice fee in addition to the Medicare rebate; and (c) cancellation from the set of Laborare and the testered with testing.



Expanded Reproductive Carrier Screen 430+ genes

Expanded Carrier Screening

Screens for 400+ genes to identify if a patient is a carrier of a genetic condition that could affect their baby.

This comprehensive screen can detect one in 44 couples at high risk of having an affected child. If a couple is found to be at risk of having an affected child they are then able to make an informed choice to accept that risk or consider a range of reproductive options such as IVF and prenatal testing to reduce the risk.



Expanded Carrier Screening

The disorders on the panel are AR and X-linked disorders which are **serious**, have **childhood-onset**, and for which there are **limited therapeutic options**.

Most patients will not have a family history.

For patients with a family history of a known mutation (such as FRAX or CF) this is not the appropriate test.



	Reproductive carrier screen (three-gene panel)	Expanded reproductive carrier screen (Beacon)
Specific request form required	No	Yes
Specimen required	Blood sample	Blood sample (or cheek swab, by arrangement)
Number of conditions screened (female)	3 common genetic conditions: Cystic fibrosis, spinal muscular atrophy, fragile X syndrome	>400 serious childhood-onset conditions with limited therapies
Number of conditions screened (male)	2 common genetic conditions: Cystic fibrosis, spinal muscular atrophy^	>350 severe childhood-onset conditions with limited therapies
Chance of a person being shown to be a carrier	~1 in 20 individuals (5%)	~3 in 4 individuals (75%)
Chance of a couple being shown to be at increased reproductive risk	~1 in 240 couples (0.4%)	~1 in 44 couples (2%)1
Medicare rebate	Yes [#]	No, (\$595* per person)
Combined report for a couple available	No	Yes
Result turnaround time for individual test (or couple tested together)	2 weeks	~ 4 weeks
Testing laboratory	Accredited Sonic Healthcare laboratory (Australia)	Accredited Fulgent Genetics laboratory (US)
Counselling		l by Sonic Genetics and found to be at high risk of fer eligible couples will accompany the results).

Reproductive carrier screen (three-gene panel)

Specific request form required

Specimen required

Blood sample

Due to the high chance of being a carrier, it is generally recommended to test both female and male at the same time.

Chance of a person being show<u>n t</u>o be a carrier ~1 in 20 individuals (5%)

There is no Medicare rebate and no free male partner testing.

Medicare rebate

If couple pregnant, strongly advise testing simultaneously due to TAT.

Testing laboratory

laboratory (Australia)

Expanded reproductive carrier screen (Beacon)

Yes

Blood sample (or cheek swab, by arrangement)

>400 serious childhood-onset conditions with limited therapies

>350 severe childhood-onset conditions with limited therapies

~ 3 in 4 individuals (75%)

~1 in 44 couples (2%)

No, (\$595* per person)

Yes

~ 4 weeks

Accredited Fulgent Genetics laboratory (US)

How do I order expanded testing?



Standard Clinpath or request forms cannot be used for expanded testing



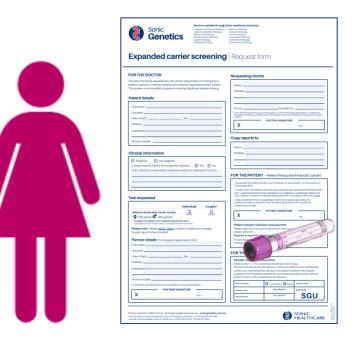
Expanded Carrier Screening form – in BP, Med Director or available at <u>www.sonicgenetics.com.au</u>

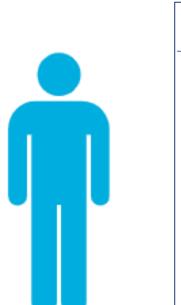


One form PER patient.

Rn	Sonic Genetics Bandaria Capatas Harry More Pathology Metourne Pathology Metourne Pathology Capata Pathology Capata Pathology Capata Pathology Capata Pathology Capata Pathology Capata Pathology	Clinpath Pathology Hobar Pathology Launceston Pathology North West Pathology Southern JML Pathology
	Expanded carrier screening	Request form
3	FOR THE DOCTOR This test should be requested by the doctor responsible for managing a patient's decision-making regarding the Beacon expanded carrier screen. This screen is not suitable for patients seeking Medicare-rebated testing.	Requesting doctor Name Address
MedicalDirector ⁻	Patient details	Phone Provider No.
	Sumame	There read the Doctor Physics/Consert section on the investee of this sequest form i confirm that the method is the purpose, scope and Imitations of the test and has given considered about the purpose, scope and Imitations of the test and has given contains: DOCTOR SIGNATURE X Date
	Phone (mobile)	Copy reports to
	Clinical information	Address
	Pregnant Not pregnant Is there a family history of any genetic disease? Yes No If Yes, please provide details of gene/mutation(s) detected, if known:	FOR THE PATIENT - Patient Privacy and Financial Consent
		FOR THE PATIENT - Patient Privacy and Financial Consent

Ordering Expanded Carrier Screening







Each patient needs a form and they must sign each others forms for a couple test.





Genetic Counselling

One counselling session with our Genetic Counsellor for all high risk couples (X-linked carrier female, AR carrier couple).

Addresses informational and psychological matters relating to preconception carrier screening results

Performed by phone/video telehealth

Letter sent from counsellor to referring doctor to advise of discussion and key points



How do I arrange genetic counselling?



Not available for all genetic results



Available for reproductive carrier screening high risk couples where at least one patient is tested through Sonic



Telehealth and once off session for the couple

GEN COUNSELLING

Genetic Counselling

Comments

NIPT indicates a possible fetal chromosome ab that have paid Sonic Healthcare for this test car counselling free of charge. The patient's doctor informing the patient of the test result, any subs for ongoing management. Sonic Healthcare off no-gap cytogenetics services for invasive pren

We are committed to maintaining the quality of grateful if the doctor caring for the patient wou clinical follow-up or test results such as the out testing. This information can be sent to your loc practice or the testing laboratory.

If genetic counselling is required, visit www.sonicgenetics.com.au/dr/NIPT/gc to dow counsellor will contact the patient within 3 bus a report after completion, or advise if the patien

CLINPATH LABORATORIES NATA NO:3307



Patie First

Preg Partr

Reproductive genetic counselling | Request form

To be eligible for this service: The referral for genetic counselling must be received within two months of the date of the latest eligible report issued by Sonic Genetics

Reproductive carrier screening: Both partners must be carriers for the same autosomal recessive disorder, or the female partner is a carrier for an X-linked disorder. At least one partner must have had carrier

Non-invasive prenatal testing (NIPT): Received a high-risk NIPT result through Sonic Genetics.

Free genetic counselling is only available to patients that have paid Sonic Genetics and had testing performed through one of the Sonic pathology practices.

testing through Sonic Genetics.

Please complete the following and fax to 1800 961 766, or email to genetic counselling@sonicgenetics.com.au. FOR THE DOCTOR On receipt of referral, the genetic counsellor will contact your patient within 3 business days to arrange an appointment.

Patient details	Clinical information
First name	Cystic fibrosis Spinal muscular atrophy Fragile X syndrome
Address	Trisomy 21 Sex chromosome aneuploidy
Phone	Requesting doctor
Pregnant Ves No Gestational age (weeks)	The patient/couple is aware that genetic counselling has been requested on their behalf and that a genetic counsellor will contact them directly to arrange counselling.
First name	Address
	Provider No



Non-Invasive Prenatal Testing

and Testing Options

Non-invasive Prenatal Testing (NIPT)

Test(s) requested

NIPT for: Trisc	omy 21, 18, 13	3	\$42	5 ☑ Yes
OPTIONS (no Fetal sex*	-			Yes
Sex chromosome aneuploidy [^] (singleton only) *Based on the presence or absence of the Y chromosome. For twin pregnancies this could indicate either two females (if absent) or at least one male. ^If sex chromosome aneuploidy is detected, the fetal sex will be revealed.				
OPTIONAL SP Genome-wid		STING (additior	nal charge)	Yes
must be selected	by the requesting of chromosome aneu	doctor prior to samp	ns and losses >7Mb ble collection. This o pregnancies. See o	option includes
Is this a 🗌 RE-	COLLECTION	I? Previous La	ab ID	•
Staff ID/Location	1 x NIPT tube	Date re-collected	Time re-collected	Re-collect PAY CAT

- Standard testing is T21, T18, T13
- Fetal sex and SCA can be added at no extra cost to patient
- Genome-wide NIPT can be added at request of doctor for additional \$70 bringing cost of NIPT to \$495

Non-invasive Prenatal Testing (NIPT)

Clinical information REQUIRED

This section must be completed for testing to proceed.

Please note: The requested clinical information is essential for test accuracy. If any of the clinical information you provide below needs updating, please notify the laboratory immediately.

NUMBER OF FETUSES

(assumed sing	leton, unless	otherwise indicated	1)		
Twin preg	gnancy				
GESTATIONAL INFORMATION					
	_//	(date) or	EDC/		

- Ensure that twin pregnancy is marked if required.
- Ensure at least one of LMP or EDC is completed and if later scan shows different date then please call laboratory to amend.

(date)

Non-invasive Prenatal Testing (NIPT)

Genetics Machine Generation States of Control of Contro	Index for any control of the	
FOR THE DOCTOR This loss for build be required by the doctor responsible for medical margement of a laware monitorial fusiting. Patient details Prist name Summa Summa Summa Summa Summa Sum	Requesting doctor Name Address Prone Prone Prone Prone Prove patients bencourselied about to puppes copy and	
Address	Initiations of the last and has glasm consent. DOCTOR SIGNATURE	
Test(s) requeste	n 10 wooke' dostation	
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Intervention and the second seco	or more fetuses presence of a demised fetus presence of maternal aneuploidy, m fetal viability.	naternal transplant or maternal malignanc
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HATT for: Takony 2 Hornocom Surgery 2 Hornocom Ho	or more fetuses presence of a demised fetus presence of maternal aneuploidy, m f fetal viability.	naternal transplant or maternal malignanc

Please ensure that you have noted this section of the form which explains some limitations of NIPT testing.

GP Shared Care GPEX

How do I order NIPT testing for my patient?



Order on a Clinpath NIPT form

Available in BP and Med Director or available in PDF form on our website.



Patient goes online to book & pay for test and attends preferred collection centre



Results returned in 3-8 business days (typically 3-5)

invasive prenata			
etails	Na	ame	
h/SexFema	e - Pregnant	onfirm that this patient has been o stations of the test and has given DOC	Provider No counselled about the purpose, scope and cortent. CTOR SIGNATURE Date
quested irisomy 21, 18, 13	Na	ame	
	U Vas		
		th /	th SoxFemale - Pregnant th / SoxFemale - Pregnant territors of the patient has been territors of the test and has been tes

Genetic Counselling for High-Risk Results



All high risk NIPT's are eligible for genetic counselling

e.	
DOUGLASS HANLY MOIR PATHOLOGY	Nipt39 Test D08 23 May 1081 (40 Yml) Lab 10 20 Y995050 Phone 24 May 1081 Address DHM
Ms Emma Solly Douglass Harly More Path Genetics Dork: 14 Offhock Avenue MACOUANE Parkins World 113	Your Ref Ms E Solty (S22416) Requested 10 Sep 2021 Collection 16 Sep 2021, 12:00 Reported 10 Mar 2022, 12:43

Non-invasive prenatal test (NIPT) report

Indication: antenatal screenir	ng test for fetal aneuploidy		
SAMPLE TYPE	ESTIMATED FETAL FRACTION	GESTATION	NO. OF FETUSES
Maternal plasma (cfDNA)	11% (sufficient for analysis)	10 weeks 1 day (at collection)	1
TEST	RESULT	RECOMMENDATION	
Trisomy 21 (T21)	Low probability	Review results with pa	tient
Trisomy 18 (T18)	Low probability	Review results with pa	itient
Trisomy 13 (T13)	Low probability	Review results with pa	itient
Fetal sex	Male	Review results with pa	atient
Sex chromosome aneuploid	y (SCA) High probability XX	(Y Genetic counselling	and additional testing
Genome-wide screen	High probability XX	(Y Genetic counselling	and additional testing

INTERPRETATION

Testing of placental cell-fine DNA from this sample shows a high proclashilly of a six chromosome anexploidy. The positive predictive value of this result an earoper six placents is between 4-90%, depending on the admornality detected. ANIFT as a scenario result should be confirmed by chromosome studies on an amricoartesis or chorinor: villous sample before making investible management discissions. Scenario (Te efficia las: involved statiction) of vibromosome material its presence of vibromosome material is interpreted as "male sec", the absence of Vibromosome material is interpreted as "female sec". The result for fetal sex does not exclude sectromosome analyzed/

NIPT IS A SCREENING TEST

Non-invasive proneal testing NNPT measures the relative abundance of cell-fine DNA (EDNA from varous chromosomes in a sample of matternal blood cellected at 10 or more weeks gestation. The test screenes for selected chromosome disorders and cipitorially sex in the fetus and placetta. NNPT is a screening test for an uncommon event. The chance that a report of 'high probability' in the fetus is correct (i.e. two positive) will vary with the pre-test probability of that disorder. The accuracy of the test dependent on the provided gestational age and parity is shown above; please contact the laboratory immediately if the information is incorrect. Please refet to g2 of this report for intertest information. The gurone-web test component screenes for are auccoard an exploidea and parall chromosome deletions and dupications >7Mb in size. There is an increased risk of analytical false positive end false negative results for this component of the NPT screen.

GEN COUNSELLING

Genetic Counselling

Comments

NIPT indicates a possible fetal chromosome about that have paid Sonic Healthcare for this test car counselling free of charge. The patient's doctor informing the patient of the test result, any subst for ongoing management. Sonic Healthcare off no-gap cytogenetics services for invasive press.

We are committed to maintaining the quality of grateful if the doctor caring for the patient woul clinical follow-up or test results such as the out testing. This information can be sent to your loc practice or the testing laboratory.

If genetic counselling is required, visit www.sonicgenetics.com.au/dr/NIPT/gc to down counsellor will contact the patient within 3 busi a report after completion, or advise if the patien

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Reproductive genetic counselling | Request form

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testing through Sonic Genetics.

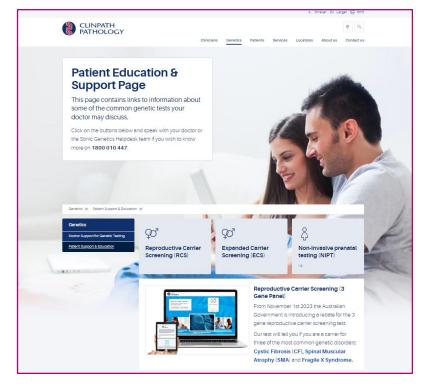
FOR THE DOCTOR Flease complete the following and fax to 1800 961 766, or email to geneticcounselling@sonicgenetics.com.au. On receipt of referral, the genetic counsellor will contact your patient within 3 business days to arrange an appointment.

Patient details	Clinical information			
First name	Please confirm which clinical condition you wish to be addressed:			
Surname Date of birth/Sex	Cystic fibrosis Fragile X syndrome	Spinal muscular atrophy		
Address	Trisomy 21	Sex chromosome aneuploidy		
	Trisomy 18	Duplication/deletion Rare autosomal aneuploidy		
Phone	Pequesting dector			
Pregnant Yes No Gestational age (weeks)	The patient/couple is awarequested on their behalf	are that genetic counselling has been f and that a genetic counsellor will contact		
Partner details (if reproductive carrier screening)	them directly to arrange of Name	counselling.		
First name				
Sumame Date of birth/ / Sex				
Address				
	Priorie			

Resources for Patients

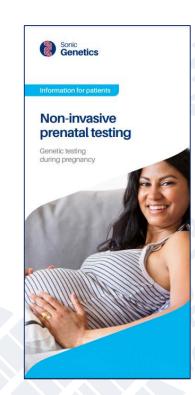
Pre-Test Resources

Clinpath Website



<section-header> Patient Cards Patient Cards Patient Resources Gretic Testing San the QR Code for Core information on Carding to the optic Cards San the QR Code for Conception for information on Carding to the optic Cardinal Cardinal Conception Cardinal Cardinal Conception Cardinal Cardinal Conception Cardinal Cardinal Conception Cardinal Cardina Cardinal Cardinal Cardinal Cardinal Cardinal Cardinal Cardinal

Brochures



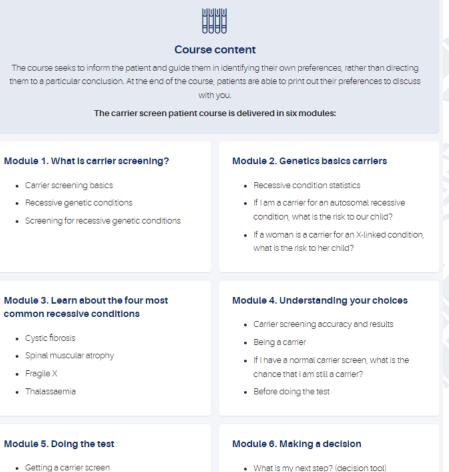
GP Shared Care GPEX

Carrier Screening Education



Carrier Screening Education





Completing the course

- · Getting a carrier screen
- Practical questions about carrier screening

Carrier Screening Education

ACRRM CPD ACCREDITED ACTIVITY

2023-2025



0

hours

Education Activitie:

2

Reviewing Performance

0

hours

This course can be used as a refresher for CPD hours.



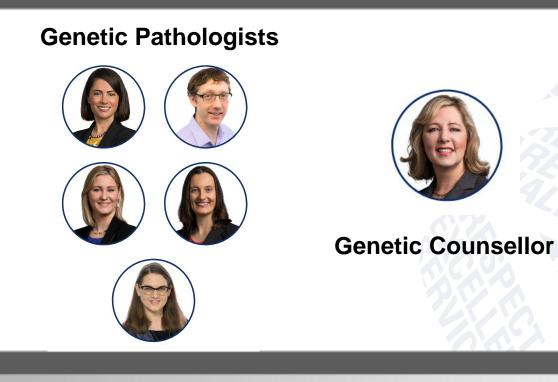


Further Support

Your Local Support Team:



Katelyn Henry



Sonic Genetic Support Team



Key Contacts



Katelyn Henry Genetics Business Manager (SA)

M | 0408 819 430 E | khenry@clinpath.com.au For more information including access to Dr. support page visit www.clinpath.com.au/genetics/



Doctor Priority Phone line 8366 2111

Sonic Genetics Helpdesk 1800 010 447

