Appendix 1





What are my options regarding prenatal screening tests?

► Who might consider being screened?

All pregnant women can choose to have screening. The risk of Trisomy 21 (T21), Trisomy 18 (T18) and Trisomy 13 (T13) increases with the woman's age.



What is Trisomy 21 (or Down syndrome)?

- o It is caused by having an extra copy of chromosome 21.
- People with T21 have intellectual disabilities that vary from slight to moderate, but are sometimes serious, with poor muscle tone, very supple joints, greater risk of vision, hearing defects, cardiac and/or gastro-intestinal defects.
- o 60% of children with T21 require specialized home care.
- o Some adults with T21 have jobs and are almost completely independent.
- People with T21 can develop meaningful emotional relationships and fulfilling lives for themselves, their families and friends.

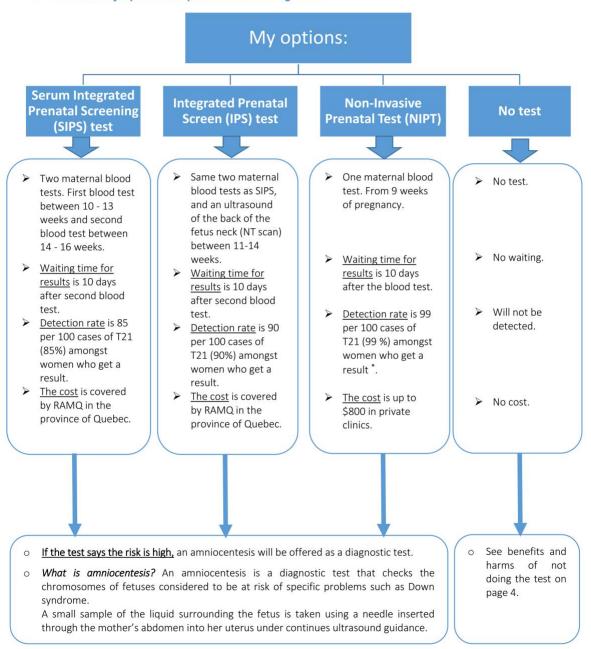
What are Trisomy 18 and Trisomy 13?

- o T18 and T13 are caused by having an extra copy of chromosome 18 or 13.
- \circ $\;$ Many pregnancies with T18 and T13 will be miscarried or result in the fetus dying in utero.
- Babies born with T18 and T13 rarely live more than a few months because of serious heart and brain defects, and poor growth before and after birth.

A decision to make:

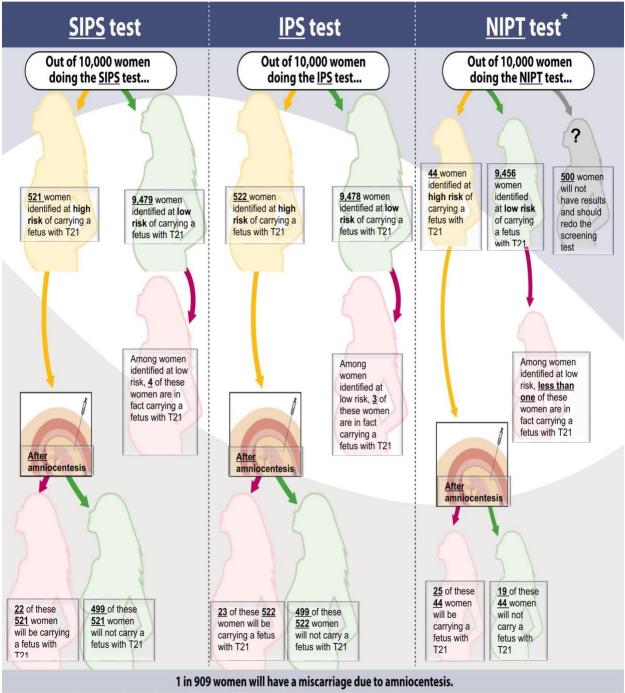
- Doing and not doing the test are both acceptable choices. We suggest that you:
 - o Base your decision on the best scientific evidence and on your values and preferences.
 - $\circ\quad$ Share the decision with your health professional, and partner.

What are my options for prenatal screening tests?



^{*}About 5% of women who take the NIPT will not have results on the first try, and will have to redo the test or take a different screening test.

What can happen after the prenatal screening test?



^{*} As there are not many studies on this use of the NIPT test, these numbers are approximate.

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> What concerns me about the benefits and harms of doing the test and not doing the test?

- Review the possible benefits and harms of each test. Add any other benefits and harms that are important to you.
 Show how important each benefit and harm is to you by circling the stars (5=very important, 1=not important).

Benefits and harms of doing the prenatal screening test:								
	w important s it to you?	Harms:	How important is it to you?					
For example, out of 10,000 women who take the NIPT test, 9,456 are identified at low risk of carrying a fetus with T21. These women are reassured. Prepare to end the pregnancy or to have a child	****	False reassurance For example, 3 of the 9.478 women identified by IPS test as at low risk of carrying a fetus with T21 will actually be carrying a T21 fetus. These women will have been falsely reassured.	****					
with T21 Among the women who know they are carrying a fetus with T21, those who choose to continue the pregnancy can prepare for a child with T21. Knowing your chances of carrying a fetus with T21	****	False alarm For example, out of the 522 women identified by IPS test as being at high risk of carrying a fetus with T21, 499 are not actually carrying a fetus with T21. Many of these women experience anxiety. 1 in 909 will have a miscarriage as a result of the amniocentesis to verify screening test results.	****					
For example, out of each 10,000 women screened, 44 are identified by NIPT test as being at high risk of carrying a fetus with T21. If these women have an amniocentesis to verify the results of the screening, 25 would actually be carrying a fetus with T21. Other benefits:	****	Anxiety while waiting for results Based on previous studies, child-related anxiety levels were higher in women who chose to be screened compared to women who declined screening.	****					
Benefits and harms of not doing the pre	natal screen	> Other harms:	****					
	How important		ow important					
	is it to you?		is it to you?					
Avoid an unnecessary test Out of 10,000 women doing IPS test, 9,478 are carrying a fetus with T21. By not doing the test, 499 of 522 pregnant women (identified by IPS test as bein high risk of carrying a fetus with T21) will avoid unnecessary amniocentesis, and 1 in 909 women avoid a miscarriage caused by the amniocentesis. Stay true to your personal convictions For some women, not doing the test is in keeping of the stay	the g at an will ****	Not knowing your risk of carrying a fetus with T21 For example, out of 10,000 women who do not take the IPS screening test, 23 are carrying fetus with T21. These women cannot prepare for living with child with special needs. They may regret no having done the prenatal screening test.	***** ot a					
their personal convictions. Avoid anxiety and avoid difficult decisions such whether to end the pregnancy Women who do not take the test avoid the anxiety of - waiting for the test results.	as ****	Anxiety about the outcome of the pregnancy Women who don't take the prenatal screenir test may be anxious because they don't know their child will have T21 or not.	g					
 making a decision about whether to do amniocentesis if the test shows a high risk of T21. making a decision about ending the pregnancy. Other benefits: 	* * * * *	> Other harms:	****					

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> Which prenatal screening test should I choose?

The blue boxes on the left show the concerns about the tests that may be important to you. You can add other concerns in the last box depending on your values or opinions.

		ant each concern is to you by circling the stars (5 = very important, mportance of each of your concerns, select the best test in the right which is best for you.		nt). 1) Importance of this concern	2) Considering this concern, which test(s) do you prefer?
	SIPS: 1st blood test in 10 - 13 weeks and 2nd blood test in 14 - 16 weeks of		4		
Γ	Week of	pregnancy.	16 weeks of		SIPS
		S: 1st blood test in 10 - 13 weeks , 2nd blood test in 14 - 16 weeks, and NT scan in 11-14 weeks of pregnancy.	****	IPS	
		NIPT: From 9 weeks of pregnancy.			NIPT
	Г	SIPS: 10 days after second blood test.		Í	SIPS
ests	Waiting time for the results	IPS: 10 days after second blood test.		****	IPS
ening t		NIPT: 10 days after blood test.			
scree	Datastian	SIPS: 85 per 100 cases of T21 (85%) among women who do	o the test.		SIPS
prenatal screening tests	Detection rate of each — test	IPS: 90 per 100 cases of T21 (90%) among women who do	the test.	****	IPS
	Lest	NIPT: 99 per 100 cases of T21 (99%) among women who go	et results.		NIPT
about	Worried for nothing (risk of a false	SIPS: About 500 per 10,000 pregnancies.			SIPS
Different concerns		IPS: About 500 per 10,000 pregnancies.		****	IPS
	positives)	NIPT: About 19 per 10,000 pregnancies.			NIPT
	Cost of each	SIPS: Covered by RAMQ in province of Quebec.			SIPS
jj		IPS: Covered by RAMQ in province of Quebec.		****	IPS
	L	NIPT: Up to \$800 in private clinics.			NIPT
		SIPS:			SIPS
	Your other concerns	IPS:		****	IPS
	concerns	NIPT:			NIPT
➤ 3) Considering my concerns and their importance, I choose					
		SIPS □ IPS □		NIPT □	

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> Are you comfortable with your decision?							
S	1) Do you feel sure about the best choice for you?	Yes 🗆	No □				
U	2) Do you feel you have all the information you need to make a decision about prenatal screening test?	Yes □	No 🗆				
R	3) Are you clear about which benefits and harms matter most to you?	Yes 🗆	No 🗆				
E	4) Do you have enough support and advice to make a choice?	Yes □	No □				
© SURE test : O'Connor et Légaré, 2008.							

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Next Update:

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