MaterniT®

Non-Invasive Prenatal Testing

The most comprehensive non-invasive prenatal testing (NIPT) for your patients, offering low failure rates and reliable results early in the pregnancy.

Test Highlights

Rapid results. Earlier in pregnancy
7-10 business days from sample receipt. Sample can be drawn as early as 9 weeks gestational age[1]

Available to different types of pregnancies
Singletons, twins*, multiple gestations*, and pregnancies with vanishing twin. IVF pregnancies, donor eggs, and gestational carriers

Low non-reportable rate, fewer patient redraws
0.9%[2] overall non reportable rate

Higher success rate in individuals with higher weight
98.3% success rate in patients that weigh 200-225 lbs, and 93.5% in those that weigh 300+ lbs[3]

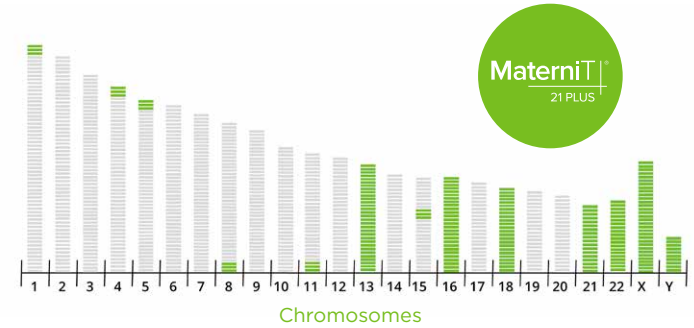
Personalized risk information with mosaicism ratio
Calculated in the event of a positive result for trisomy 13, 18 or 21 to refine your patient's risk for aneuploidy

GENOME-Flex: a NIPT high risk pathway
Genome-wide sample reanalysis after completion of MaterniT® 21 PLUS upon request

**MaterniT® GENOME available to singleton pregnancies only.*

MaterniT® 21 PLUS

MaterniT® 21 PLUS is a non-invasive prenatal test that screens for the most common trisomies (13, 18, and 21) and provides the option to screen for fetal sex, sex chromosome aneuploidies, and select clinically relevant microdeletions and rare autosomal trisomies.



Chromosomes

MaterniT® GENOME

MaterniT® GENOME is a non-invasive prenatal test that analyzes all 23 chromosome pairs for trisomy, monosomy, deletions/duplications ≥ 7Mb, select clinically relevant microdeletions, and fetal sex.

Examples of clinical scenarios where this test may be considered include high-risk pregnancies where a patient may wish to avoid a diagnostic procedure, or may not be eligible for a diagnostic procedure (i.e. oligihydramnios), IVF pregnancies conceived with a mosaic embryo, or pregnancies where a parent has a chromosomal translocation. MaterniT® GENOME discovers 30% more clinically relevant genomic variants not detectable by other NIPT options.[4]

	MaterniT® 21 PLUS	MaterniT® GENOME
Trisomy 13, 18, 21	✓	✓
Fetal Sex	✓*	✓*
Sex Chromosome Aneuploidies⁺ Includes 45,X (Turner syndrome), 47,XXY (Klinefelter syndrome), 47,XXX (Triple X syndrome), 47,XYY (XYY syndrome)	✓*	✓
Microdeletions Includes 22q11.2 deletion syndrome, 11q23 (Jacobsen syndrome), 5p15 (Cri-du-chat syndrome), 8q24 (Langer-Giedion syndrome), 1p36 deletion syndrome, 4p16 (Wolf-Hirschhorn syndrome), 15q11 (Prader-Willi syndrome; Angelman syndrome)	✓*	✓
Trisomy 16, 22	✓*	✓
Genome-wide analysis with subchromosomal copy number variants⁺ (CNVs)		✓

** Optional*

⁺ Singleton pregnancies only

Dynacare.ca/PrenatalTesting

Dynacare®
Genetics and Specialty Services

MaterniT®

MaterniT® 21 PLUS and MaterniT® GENOME provide a risk assessment. The result is not diagnostic. False positives and false negatives may occur, and each result should be considered in the context of other clinical results, ultrasound findings, and family history. Diagnostic testing, such as chorionic villus samples (CVS) or amniocentesis along with genetic counselling, is highly recommended to confirm positive NIPT results. Please note this test does not screen for all possible genetic conditions.

	MaterniT® 21 PLUS		MaterniT® GENOME	
Region/Condition	Sensitivity	Specificity	Sensitivity	Specificity
Trisomy 21 (Down syndrome)	99.1%[2,5]	99.9%[2,5]	99.4%[17]	99.0%[17]
Trisomy 18	>99.9%[5]	99.6%[5]	95.8%[17]	99.5%[17]
Trisomy 13	91.7%[5]	99.7%[5]	98.7%[17]	98.5%[17]
Fetal Sex	99.4% accuracy[6]		99.6% accuracy[18]	
Sex Chromosome Aneuploidies	96.2%[7]	99.7%[7]	84.6 - 100%[17]	96.3 - 100%[17]
Microdeletions	The sensitivity can range from 60% to >91%, depending on the size of the deletion[8-16]		The sensitivity can range from 51% to >97%, depending on the size of the deletion[1,17,19,20]	
Genome-wide aneuploidies	N/A		99.5%[18]	>99.9%[18]
CNVs ≥ 7Mb	N/A		97.7%[18]	>99.9%[18]

How to Order

1. **Complete Requisition**
   To access the MaterniT® prenatal test requisition, visit **Dynacare.ca/MaterniT-Requisition**

2. **Sample Collection**
   To provide a sample, your patient can visit a Dynacare laboratory, a Dynacare external partner collection site, or on site at your clinic.

3. **Access Results**
   You will receive results within 7-10 business days after sample receipt.

Questions?

Contact us at **DynacareGenetics@dynacare.ca** or call our Customer Care Team at **888.988.1888**

References

1. Internal data
2. Palomaki GE, Deciu C, Lambert-Messerlian GM, et al. DNA sequencing of maternal plasma to detect Down syndrome: An international clinical validation study. Genet Med. 2011;13(11):913-920.
3. Wardrop J, Xu C, Almasri E, et al. Success of NIPT based on maternal weight and gestational age. Clinical poster presented at NSGC annual meeting, Utah 2019.
4. Boomer T, Caldwell S, Almasri E, et al. Genome-wide cfDNA screening: Trends and lessons from >40,000 samples. Poster presented at: 2018 American College of Medical Genetics and Genomics Annual Clinical Genetics Meeting; April, 2018; Charlotte, NC.
5. Palomaki GE, Deciu C, Kloza EM, et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13, as well as Down syndrome: An international collaborative study. Genet Med. 2012;14(3):296-305.
6. Mazloom, A, Oeth P, Wang T, et al. Accuracy of noninvasive prenatal sex determination using massively parallel sequencing in samples from a large clinical validation study. Poster presented at American Society of Human Genetics annual meeting; 2012 Nov 6-10; San Francisco, CA.
7. Mazloom AR, Džakula Ž, Oeth P. et al. Noninvasive prenatal detection of sex chromosomal aneuploidies by sequencing circulating cell-free DNA from maternal plasma. Prenat Diagn. 2013;33(6):591-7.
8. Zhao C, et al. Detection of fetal subchromosomal abnormalities by sequencing circulating cell-free DNA from maternal plasma. PLoSone. In press.
9. Online Mendelian Inheritance in Man website www.OMIM.org. Accessed May 21, 2014.
10. Heilstedt HA, et al. Physical map of 1p36, placement of breakpoints in monosomy 1p36, and clinical characterization of the syndrome. Am J Hum Genet. 2003;72(5):1200-2012.
11. Lüdecke HJ Molecular definition of the shortest region of deletion overlap in the Langer-Giedion syndrome. Am J Hum Genet. 1991;49(6):1197-1206.
12. Maas NM, et al. Genotype-phenotype correlation in 21 patients with Wolf-Hirschhorn syndrome using high resolution array comparative genome hybridisation (CGH). J Med Genet. 2008;45(2):71-80.
13. McDonald-McGinn DM, et al. Genetic counseling for the 22q11.2 deletion. Dev Disabil Res Rev. 2008;14(1):69-74.
14. Kim SJ, et al. Unique and atypical deletions in Prader-Willi syndrome reveal distinct phenotypes. Eur J Hum Genet. 2012;20(3):283-290.
15. Zhang X, et al. High-resolution mapping of genotype-phenotype relationships in cri-du-chat syndrome using array comparative genomic hybridization. Am J Hum Genet. 2005;76(2):312-326.
16. Mattina T, et al. Jacobsen syndrome. Orphanet J Rare Dis. 2009;4:9. doi: 10.1186/1750-1172-4-9.
17. Soster E, Boomer T, Hicks S, et al. Three years of clinical experience with a genome-wide cfDNA screening test for aneuploidies and copy-number variants. Genet Med. 2021; 23(7); 1349-1355.
18. Lefkowitz R, Tynan J, Liu T, et al. Clinical validation of a non-invasive prenatal test for genome-wide detection of fetal copy number variants. Am J Obstet Gynecol; 2016; 215(2); 227.e1-227.e16.
19. Mazloom AR, et al. Karyotype-level noninvasive prenatal testing by sequencing of circulating cell-free DNA from maternal plasma. International Society of Prenatal Diagnosis Annual Meeting. July 2015.
20. Zhao C, et al. Detection of Fetal Subchromosomal Abnormalities by Sequencing Circulating Cell-Free DNA from Maternal Plasma. Clin Chem. 2015; 61(4):608-616.